ANDA 213614/S-017

PRIOR APPROVAL SUPPLEMENT
APPROVAL

Mankind Pharma Limited
c/o Lifestar Pharma LLC (a Mankind Group Company)
1200 MacArthur Blvd.
Mahwah, NJ 07430
Attention: Parimal Upadhyay, Authorized U.S. Agent
Sr. Vice President, Business Development and Portfolio

Dear Sir or Madam:

This is in reference to your supplemental abbreviated new drug application (sANDA) received for review on July 12, 2023, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for Alosetron Hydrochloride Tablets.

The sANDA, submitted as "Prior Approval Supplement," provides for proposed modifications to the approved Alosetron Shared System Risk Evaluation and Mitigation Strategy (REMS).

We have completed the review of this sANDA, and it is **approved**.

RISK EVALUATION AND MITIGATION STRATEGY (REMS) REQUIREMENTS

In order to minimize burden on the healthcare delivery system of complying with the REMS, we determined that you were required to make the REMS modifications outlined in our REMS Modification Notification letter dated June 8, 2023.

Elements to Assure Safe Use: We have determined that elements to assure safe use are no longer necessary based on the following data:

- The recent REMS assessment reports have indicated acceptable knowledge and understanding among prescribers and patients related to the goal and objectives of the REMS despite an ongoing downward trend in completion of the voluntary REMS training program by prescribers.

- Adverse event reporting of ischemic colitis and serious complications of constipation has been stable, and an increase in severe outcomes has not been observed since the REMS was modified in 2016.

- An analysis of new female users of alosetron in the Sentinel Distributed Database from 2016 to 2020 found the rate of ischemic colitis for alosetron to be consistent with that listed in the Prescribing Information.

- There has been an ongoing downward trend in the utilization of all alosetron products.

Therefore, because the elements to assure safe use are no longer necessary to ensure the benefits of the drug outweigh the risks, a REMS is no longer required for alosetron.

REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL

Under applicable statutes, regulations, and guidances, your ANDA may be subject to certain requirements and recommendations post approval, including requirements regarding changes to approved ANDAs, postmarketing reporting, promotional materials, and annual facility fees, among others. For information on post-approval requirements and recommendations for ANDAs and a list of resources for ANDA holders, we refer you to https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/requirements-and-resources-approved-andas.

If you have any questions, call CAPT Stacy Barley, REMS Coordinator, at (301) 796-2137.

Sincerely,

{See appended electronic signature page}

Debra M. Catterson, RPh
Deputy Director
Division of Clinical Safety and Surveillance
Office of Safety and Clinical Evaluation
Office of Generic Drugs
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

DEBRA M CATTERSON
09/08/2023 10:27:01 AM