DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 011287/S-026

SUPPLEMENT APPROVAL/
RELEASE FROM POSTMARKETING REQUIREMENT

Concordia Pharmaceuticals, Inc.
C/O Mapi USA
Attention: Mandy Dorsey
2343 Alexandria Drive
Suite 100
Lexington KY, 40504

Dear Ms. Dorsey:

Please refer to your Supplemental New Drug Application (sNDA) dated and received February 2, 2017, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Kayexalate (sodium polystyrene sulfonate) powder for suspension, 453.6 g jar.

This Prior Approval supplemental new drug application provides for revisions to labeling to address use with other orally administered medications. This supplement also provides for revisions to labeling to comply with the Physician's Labeling Rule (PLR).

APPROVAL & LABELING

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

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), 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 include 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).

POSTMARKETING REQUIREMENTS

We also refer to our correspondence dated April 18, 2016, acknowledging your post marketing requirement under Section 505(o)(3) of the FDCA;

3073-1 *In vitro* drug-drug interaction (DDI) studies in media mimicking physiological conditions (i.e., at pH 1.2, 4.5 and 6.8), including appropriate replicates.

Final Protocol Submission:	02/17
Study/Trial Completion:	07/18
Final Report Submission:	01/19

We have reviewed your submission and have determined that you are released from the above requirement as it is no longer needed because the labeling revisions approved in this supplement are sufficient to mitigate the risk.

This completes all of your postmarketing requirements acknowledged in our April 18, 2016 letter.

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, please call Michael Monteleone, Regulatory Project Manager, at (301) 796-1952.

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, PharmD
Deputy Director for Safety
Division of Cardiovascular and Renal Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

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

/s/

MARY R SOUTHWORTH
07/28/2017