DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 90-600

Kremers Urban Development Co.
Attention: Rachel Schwipps
Regulatory Affairs Manager
1101 C Avenue West
Seymour, IN 47274

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated April 30, 2008, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for GlycoLax (Polyethylene Glycol 3350 Powder for Solution), packaged in Multiple-dose bottles containing 17 grams/Scoopful And Single-dose Pouches.

Reference is also made to your amendments dated February 12, May 15, May 26, June 1, August 19, and October 1, 2009.

We have completed the review of this ANDA and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved, effective on the date of this letter. The Division of Bioequivalence has determined your Polyethylene Glycol 3350 Powder for Solution, 17 grams/Scoopful, to be bioequivalent to the reference listed drug, Miralax Powder for Solution, 17 grams/Scoopful, of Schering Plough Healthcare Products, Inc.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Within 14 days of the date of this letter, submit updated content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the approved labeling. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission as "***Miscellaneous Correspondence - SPL for Approved ANDA 90-600.***"

Sincerely yours,

{See appended electronic signature page}

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
ANDA-90600	ORIG-1	KREMERS URBAN DEVELOPMENT CO	POLYETHYLENE GLYCOL 3350

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

/s/

ROBERT L WEST
10/06/2009
Deputy Director, for Gary Buehler