DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

sANDA 075155/S-034

APPROVAL

Kremers Urban Pharmaceuticals Inc.
Attention: Kurt Zimmer
Regulatory Affairs Manager
1101 C Avenue West
Seymour, IN 47274

Dear Sir:

Please refer to your Supplemental Abbreviated New Drug Application (sANDA) dated August 27, 2010, received August 30, 2010, submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act, regarding your abbreviated new drug application (ANDA) for Isosorbide Mononitrate Extended-release Tablets USP, 30 mg, 60 mg, and 120 mg.

We acknowledge receipt of your amendments dated September 17, 2010; and May 30, June 17, and July 24, 2014.

The supplemental ANDA, submitted as "Changes Being Effected in 30 Days," provides for:

> Addition of 30-count (60mg) and 90-count (30 mg and 60 mg) bottle packaging configurations.

We have completed our review of this sANDA, as amended, and it is approved.

We remind you that you must comply with the requirements for the approved ANDA described in 21 CFR 314.80-81.

The Generic Drug User Fee Amendments of 2012 (GDUFA) (Public Law 112-144, Title III) established certain provisions with respect to self-identification of facilities and payment of annual facility fees. Your ANDA identifies at least one facility that is subject to the self-identification requirement and payment of an annual facility fee. Self-identification must occur by June 1 of each year for the next fiscal year. Facility fees must be paid each year by the date specified in the Federal Register notice announcing facility fee amounts. All finished dosage forms (FDFs) or active pharmaceutical ingredients (APIs) manufactured in a facility that has not met its obligations to self-identify or to pay fees when they are due will be deemed misbranded. This means that it will be a violation of federal law to ship these products in interstate commerce or to import them into the United States. Such violations can result in prosecution of those responsible, injunctions, or seizures of misbranded products. Products misbranded because of failure to self-identify or pay facility fees are subject to being denied entry into the United States.

The material submitted is being retained in our files.

Sincerely yours,

{See appended electronic signature page}

CAPT Jason J.Y. Woo, M.D., M.P.H.
Acting Director, Office of Regulatory Operations
Office of Generic Drugs
Center for Drug Evaluation and Research

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

09/24/2014

Associate Director for Review Quality, for
Jason Woo, M.D., M.P.H.