ANDA 75-395 March 16, 2000

KV Pharmaceutical Company
Attention: Herbert G. Luther, Ph.D.
2503 South Hanley Road
St. Louis, MO 63144

Dear Sir:

This is in reference to your abbreviated new drug application dated June 1, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Isosorbide Mononitrate Extended-release Tablets, 30 mg, 60 mg and 120 mg.

Reference is also made to your amendments dated September 28, and October 30, 1998; and January 6, January 28, February 16, March 1, March 2, and March 8, 2000.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Isosorbide Mononitrate Extended-release Tablets, 30 mg, 60 mg, and 120 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Imdur® Extended-release Tablets, 30 mg, 60 mg, and 120 mg, respectively, of Schering Corporation). Your dissolution testing should be incorporated into the stability and quality control program using the same method as proposed in your application. The "interim" dissolution test(s) and tolerances are:

The dissolution testing should be conducted in 900 mL of simulated intestinal fluid (SIF), pH 7.5, at 37° C using USP Apparatus 2 (paddle) at 50 rpm. For the 30 mg and 60 mg strengths, dissolution testing should also be conducted on the half tablet. The test product should meet the following tentative specifications:

Time	Whole Tablet	Half Tablet
[		]
[		]

[ ]
[ ]

The "interim" dissolution test and tolerances should be finalized by submitting dissolution data for the first three production size batches in a supplemental application. A “Special Supplement - Changes Being Effected” (zero) should be submitted if there are no revisions proposed to the “interim” specifications or when the final specifications are tighter than the “interim” specifications. In all other instances a Prior Approval supplement should be submitted.

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

Post-marketing reporting requirements for this abbreviated application 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.

We request that you submit, in duplicate, any proposed advertising or promotional copy, which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Validation of the regulatory methods has not been completed. It is the policy of the Office not to withhold approval until the validation is complete. We acknowledge your commitment to satisfactorily resolve any deficiencies that may be identified.

Sincerely yours,

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