ANDA 75-604 April 10, 2002

Andrx Pharmaceuticals, Inc.
Attention: Diane Servello
4955 Orange Drive
Ft. Lauderdale, FL 33314

Dear Madam:

This is in reference to your abbreviated new drug application dated March 22, 1999, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Potassium Chloride Extended-release Tablets USP, 10 mEq and 20 mEq.

Reference is also made to your amendments dated April 4, 2000; November 12, 2001; and January 21, March 8, March 26 and March 28, 2002.

The listed drug product (RLD) referenced in your application, K-Dur® Extended-Release Tablets of Key Pharmaceuticals Inc., is subject to a period of patent protection which expires on September 5, 2006, (U.S. patent 4,863,743, the '743 patent). Your application contains a Paragraph IV Certification to the '743 patent under Section 505(j)(2)(A)(vii)(IV) of the Act stating that the patent will not be infringed by your manufacture, use, or sale of this drug product. Section 505(j)(5)(B)(iii) of the Act provides that approval shall be made effective immediately unless an action is brought for infringement of the patent which is the subject of the certification before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received. You have notified FDA that Andrx Pharmaceuticals, Inc. (Andrx) has complied with the requirements of Section 505(j)(2)(B) of the Act, and that no action for patent infringement was brought against Andrx within the statutory forty-five day period.

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 Potassium Chloride Extended-release Tablets USP,

10 mEq and 20 mEq, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (K-Dur® Extended-Release Tablets, 10 mEq and 20 mEq, respectively, of Key Pharmaceuticals, Inc. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application. The "interim" dissolution specifications are as follows:

The dissolution testing should be conducted in _____

The test products should meet the following specifications:

Time, hr	Amount Dissolved
_____	_____
_____	_____

These "interim" dissolution test(s) and tolerances should be finalized by submitting dissolution data for the first three production size batches. Data should be submitted as a Special Supplement – Changes Being Effected when there are no revisions to the "interim" specifications or when the final specifications are tighter than the "interim" specifications. In all other instances, the information should be submitted in the form of a Prior Approval Supplement.

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.

Sincerely yours,

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