ANDA 74-812

May 11, 1999

ESI Lederle, Inc.
Attention: Nicholas C. Tantillo
401 N. Middletown Road
Pearl River, NY 10965-1299

Dear Sir:

This is in reference to your abbreviated new drug application dated December 22, 1995, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Potassium Chloride Extended-release Tablets USP, 1500 mg (20 mEq).

Reference is also made to your amendments dated May 14, 1997; October 19 (2 submissions), November 13, and December 4, 1998; and March 11, March 12, and April 27, 1999.

We have completed the review of this abbreviated application and have concluded that based upon the information you have presented to date, the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is **tentatively approved.** This determination is based upon information available to the Agency at this time (i.e., information in your application and the status of current good manufacturing practices (CGMPs) of the facilities used in the manufacture and testing of the drug product), and is subject to change on the basis of new information that may come to our attention.

The listed drug product (RLD) referenced in your application, K-Dur 20 Extended-release Tablets of Key Pharmaceuticals, Inc., is subject to a period of patent protection which expires on September 5, 2006, (U.S. Patent No. 4,863,743 [the ‘743 patent]). Your application contains a patent certification under Section 505(j)(2)(A)(vii)(IV) of the Act stating that your manufacture, use, or sale of this drug product will not infringe on the ‘743 patent and that the patent is invalid or unenforceable. Section 505(j)(5)(B)(iii) of the Act provides that approval of an abbreviated application shall be made effective immediately unless an action for patent infringement is brought before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(I) is received by both the holder of the

new drug application for the RLD and the patent holder(s). You have notified the Agency that ESI Lederle Inc. (Lederle) has complied with the requirements of Section 505(j)(2)(B) of the Act and that the patent holder initiated a patent infringement action against Lederle in the United States District Court for the Eastern District of Pennsylvania (Civil Action No. 96-4510). You have also notified the Agency that on June 29, 1998, the court dismissed the action without prejudice terminating the litigation between the parties.

Furthermore, the Act provides that approval of an abbreviated application that contains a certification described in section 505(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification"), and that is for a drug product for which a previous abbreviated application has been submitted which also contains a Paragraph IV Certification, shall be made effective not earlier than one hundred and eighty days after:

a. the date the Secretary receives notice of the first commercial marketing of the drug under the previous application, or

b. the date of a decision of a court holding the patent which is the subject of the certification to be invalid or not infringed, whichever occurs first (Section 505(j)(5)(B)(iv)).

Please note that an abbreviated application for Potassium Chloride Extended-release Tablets USP, 1500 mg (20 mEq) containing a Paragraph IV Certification was accepted for filing by this office prior to the filing of your application. Accordingly your application will be eligible for final approval beginning on the date that is one hundred and eighty (180) days after the first commercial marketing of the drug product under the previous application, or the date of a court decision described under Section 505(j)(5)(B)(iv), whichever is earlier. We refer you to the Agency's recently issued guidance document entitled "180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments" (June 1998), for additional information.

Because the Agency is granting a tentative approval for this application, please submnit an amendment at least 60-days but not more than 90-days prior to the date you believe your application will be eligible for final approval. This amendment should identify changes, if any, in the conditions under which the drug product was tentatively approved, and should include updated information such as final-printed labeling, chemistry, manufacturing, and controls data, as appropriate. Alternatively if applicable, this amendment should also be submitted to state

that no changes were made to the terms of this application since the date of this tentative approval. This amendment should be designated clearly in your cover letter as a MINOR amendment. In addition to, or instead of this amendment, the Agency may request at any time prior to the date of final approval of this application that you submit an amendment containing the information described above. Failure to submit either or, if requested, both amendments, may result in rescission of the tentative approval status of your application, or may result in a delay in the issuance of the final approval letter.

Any changes in the conditions outlined in this abbreviated application as well as changes in the status of the manufacturing and testing facilities' compliance with current good manufacturing practices (CGMPs) are subject to Agency review before final approval of the application will be made.

The drug product that is the subject of this abbreviated application may not be marketed without final Agency approval under Section 505 of the Act. The introduction or delivery for introduction into interstate commerce of this drug product before the final approval date is prohibited under section 501 of the Act. Also, until the Agency issues the final approval letter, this drug product will not be listed in the Agency's "Approved Drug Products with Therapeutic Equivalence Evaluations" list, commonly referred to as the “Orange Book”.

Prior to submitting the amendment(s), please contact Bonnie McNeal, Project Manager, at (310) 827-5848, for further instructions.

Sincerely yours,

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research