ANDA 75-410 May 3, 2001

Kremers Urban Development Company
Attention: John Vaughan
6140 W. Executive Drive
Mequon, WI 53092

Dear Sir:

This is in reference to your abbreviated new drug application dated July 2, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Omeprazole Delayed-Release Capsules, 10 mg and 20 mg.

Reference is also made to your amendments dated October 6 and December 29, 1998; April 15, June 4, September 16, 1999; February 8, May 12, June 2, July 13, September 14, November 30, and December 12, 2000; and February 8, March 5, and May 2, 2001.

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. Therefore, 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). The determination is subject to change on the basis of new information that may come to our attention. This letter does not address notice issues related to the 180-day exclusivity provisions under section 505(j)(5)(B)(iv) of the Act.

The listed drug product referenced in your application, Prilosec Delayed-release Capsules of AstraZeneca LP, is subject to periods of patent protection which expire on May 30, 2005, (U.S. Patent No. 4,636,499; April 20, 2007, (U.S. Patent Nos. 4,786,505 and 4,853,230); February 2, 2010, (U.S. Patent No. 5,093,342); February 4,2014, (U.S. Patent Nos. 5,599,794 and 5,629,305); October 9, 2018, (U.S. Patent Nos. 6,147,103, 6,166,213, and 6,191,148) and November 10, 2018, (U.S. Patent

No. 6,150,380). Please note that under Section 505A of the Act, on May 1, 2001, the agency granted the NDA holder, AstraZeneca LP, six months of additional marketing exclusivity (pediatric exclusivity). This exclusivity will effectively extend each of the patents noted above by an additional 6-months.

We note that your application contains patent statements under Section 505 (j)(2)(A) (viii) of the Act indicating that the '342, '794, and '305 patents are for method of use patents, and that these patents do not claim any of the proposed indications for which you are seeking approval. In addition, your application contains Paragraph IV Certifications to the '499, '505, '230, '103, '380, '213, and '148 patents 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 these patents or that these patents are 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 is brought for infringement of one or more of these patents which are the subject of the certifications before the expiration of forty-five days from the date the notice provided under paragraph (2)(B)(i) is received by the NDA and patent holder(s). You have notified the agency that Kremers Urban Development Company (KUDCo) complied with the requirements of Section 505(j) (2)(B) of the Act, and as a result litigation is underway in the United States District Court for the Eastern District of Wisconsin involving challenges to the '499, '505, '230, '794, '305, and '342 patents (Astra Aktiebolag, Aktiebolaget Hassle, KBI-E Inc., KBI Inc. and AstraZeneca, L.P. v. Kremers Urban Development Co., and Schwarz Pharma Inc., Civil Action No. 99-C-0131). This litigation was subsequently consolidated with similar litigation pending in various United States District Courts and now resides in the United States District Court for the Southern District of New York. Therefore, final approval cannot be granted until:

1. a. the expiration of the 30-month periods provided for in section 505(j)(5)(B)(iii) since the date of receipt of the 45-day notices required under section 505(j)(2)(B)(i), unless the court has extended or reduced the periods because of the failure of either party to reasonably cooperate in expediting the action, or,

b. the date of a court decision [505(j)(5)(B)(iii)(I), (II), or (III)], which has been interpreted by the Agency to mean the date of the final order or judgement of that court from which no appeal can be or has been taken, or,

c. the patents have expired, and

2. The Agency is assured there is no new information that would affect whether final approval should be granted.

Because the Agency is granting a tentative approval for this application, when you believe that your application may be considered for final approval, you must amend your application to notify the Agency whether circumstances have or have not arisen that may affect the effective date of final approval. Your amendment must provide:

1. A copy of a final order or judgement from which no appeal may be taken (which might not be the one from the district court), or a settlement agreement between the parties, whichever is applicable, or a licensing agreement between you and the patent holder, or any other relevant information, and

2. a. updated information related to final-printed labeling or chemistry, manufacturing and controls data, or any other change in the conditions outlined in this abbreviated application, or

b. a statement that no such changes have been made to the application since the date of tentative approval.

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

In addition to, or instead of, the amendments referred to above, the Agency may, at any time prior to the final date of approval, request that you submit amendments containing the information requested above.

Failure to submit either or both amendments may result in rescission of this tentative approval determination, or delay in issuance of the final approval letter.

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 before the effective 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.

The amendment should be designated as a MINOR AMENDMENT in your cover letter. Before you submit the amendment, please contact Kassandra Sherrod, R.Ph., Project Manager, at 301-827-5849, for further instructions.

Sincerely yours,

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