ANDA 76-164 March 8, 2002

Purepac Pharmaceutical Co.
Attention: Joan Janulis, R.A.C.
200 Elmora Avenue
Elizabeth, NJ 07207

Dear Madam:

This is in reference to your abbreviated new drug application dated April 20, 2001, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Lisinopril Tablets USP, 20 mg, 30 mg and 40 mg.

Reference is also made to your amendments dated August 22, November 2 and December 20, 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 of the facilities used in the manufacturing and testing of the drug product) and is therefore subject to change on the basis of new information that may come to our attention.

The reference listed drug product (RLD) upon which you have based your application, Zestril® Tablets of AstraZeneca UK Ltd. is currently subject to a period of patent protection (U.S. Patent No. 4,374,829, the “829 patent”). Your application contains a Paragraph III Certification under Section 505(j)(2)(A)(vii)(III) of the Act stating that you will not market this product prior to the expiration of the ‘829 patent. As noted in the current edition of the Agency’s publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluations”, the “Orange Book”, and this patent was scheduled to expire on December 29, 2001. However, Section 111 of Title I of the Food and Drug Administration Modernization Act of 1997

(the Modernization Act) created Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a). Section 505A permits the sponsor of the RLD to obtain an additional six months of marketing exclusivity if, in accord with the statute, the sponsor submits data previously requested by the Agency relating to the use of the drug in the pediatric population. The RLD holder has submitted data to support the use of Zestril Tablets in a pediatric population. The Agency's Pediatric Exclusivity Board has determined that the data support the granting of 6-months of pediatric exclusivity to Zestril Tablets. Consequently, the awarding of this exclusivity will effectively lengthen the life of the '829 patent for an additional 6 months. Therefore, final approval of your application may not be made effective pursuant to 21 U.S.C. 355(j)(5)(B)(ii) of the Act until both the '829 patent and the additional exclusivity period granted to Zestril Tablets have expired; i.e., currently June 29, 2002.

Because the Agency is granting a tentative approval for this application, please submit 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 product was tentatively approved, and should include updated information such as labeling, chemistry, manufacturing, and controls data as appropriate. An amendment should be submitted even if none of these changes were made. This submission should be designated clearly in your cover letter as a MINOR AMENDMENT. In addition to this amendment, the Agency may request at any time prior to the final date of approval that you submit an additional 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 significant 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.

Please note that this drug product 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 and 21 U.S.C. 331(d). Also, until the Agency issues the final approval letter, this drug product will not be deemed approved for marketing under 21 U.S.C. 355 and will not be listed in the "Approved Drug Products with Therapeutic Equivalence Evaluations" list (the "Orange Book"), published by the Agency. Should you believe that there are grounds for issuing the final approval letter prior to June 29, 2002, you should amend your application accordingly.

At the time you submit any amendments, you should contact Timothy Ames, Project Manager, at 301-827-5848, for further instructions.

Sincerely yours,

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