

ANDA 75-369 (10 mg and 20 mg)  
2000

August 22,

75-370 (2.5 mg and 5 mg)

Danbury Pharmacal, Inc.  
Attention: Ann Mullarkey  
U.S. Agent for KRKA, d.d., Novo mesto  
Mt. Ebo Drive South, Route 22  
Brewster, NY 10509

Dear Madam:

This is in reference to your abbreviated new drug applications dated April 30, 1998, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Enalapril Maleate Tablets USP.

Reference is also made to the Tentative Approval letters issued by this office on January 29, 1999 and March 28, 2000, and to your amendments dated June 5, 2000.

We have completed the review of these abbreviated applications and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the applications are approved. The Division of Bioequivalence has determined your Enalapril Maleate Tablets, USP 2.5 mg, 5 mg, 10 mg, and 20 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug [Vasotec<sup>7</sup> Tablets, 2.5 mg, 5 mg, 10 mg and 20 mg, respectively, of Merck Research Laboratories]. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your applications.

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

Post-marketing reporting requirements for these abbreviated applications 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  
Acting Director  
Office of Generic Drugs  
Center for Drug Evaluation and Research

