



ANDA 74-056

Food and Drug Administration  
Rockville MD 20857

Lemmon Company  
Attention: Deborah A. Jaskot  
650 Cathill Rd  
Sellersville, PA 18960

JAN 18 1995

Dear Madam:

This is in reference to your abbreviated new drug application dated April 19, 1991, submitted pursuant to Section 505(j) of the Food, Drug, and Cosmetic Act for Atenolol Tablets, 50 mg and 100 mg.

Reference is also made to your amendments dated June 1, June 30, July 13, and December 29, 1994.

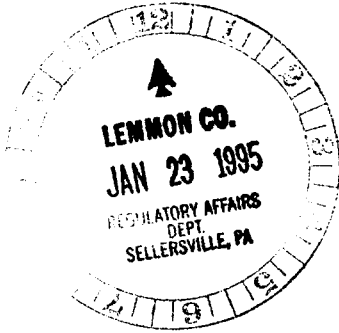
We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Atenolol Tablets, 50 mg and 100 mg, to be bioequivalent and, therefore, therapeutically equivalent to those of the listed drug (Tenormin<sup>®</sup> Tablets, 50 mg and 100 mg, respectively, of Zeneca Pharmaceuticals). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under 21 CFR 314.70, 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. 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-240). 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-240) with a completed Form FD-2253 at the time of their initial use.



Sincerely yours,

A handwritten signature in dark ink, appearing to read "Sporn" followed by a flourish.

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