

September 4, 1998

Watson Laboratories, Inc.  
Attention: Mr. Ron Lapré  
311 Bonnie Circle  
Corona, CA 91720



Dear Mr. Lapré:

This is in reference to your abbreviated new drug application dated April 1, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Pentoxifylline Extended-release Tablets, 400 mg.

Reference is also made to your amendments dated November 6, 1997 and May 18, June 12, and August 21, 1998.

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 Pentoxifylline Extended-release Tablets, 400 mg to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Trental® Tablets, 400 mg, of Hoechst Marion Roussel, Inc.).

Your dissolution testing should be incorporated into the stability and quality control program using the same method as proposed in your application. The "interim" dissolution test(s) and tolerances are:

The dissolution testing should be conducted in 900 mL of water at 37°C using USP 23 apparatus II (paddle) at 75 rpm, and should meet the following "interim" dissolution specifications:

- 1 hour
- 6 hours
- 12 hours
- 20 hours

The "interim" dissolution test(s) and tolerances should be finalized by submitting dissolution data for the first three production size batches in a supplemental application. The

supplemental application should be submitted under 21 CFR 314.70 (c)(1) when there are no revisions to the interim specifications or when the final specifications are tighter than the interim specifications. In all other instances the supplement should be submitted under 21 CFR 314.70(b)(2)(ii).

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 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,

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