

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

Application Number: 74-962

Trade Name: Pentoxifylline Extended release Tablets 400mg

**Generic Name: Pentoxifylline Extended release Tablets
400mg**

Sponsor: Upsher-Smith Laboratories, Inc.

Approval Date: March 31, 1999

**INDICATION(s): for the treatment of patients with
intermittent claudication on the basis of chronic occlusive
arterial disease of the limbs.**

137

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION: 74-962

CONTENTS

	Included	Pending Completion	Not Prepared	Not Required
Approval Letter	X			
Tentative Approval Letter				X
Approvable Letter				X
Printed Labeling	X			
Medical Review(s)				
Chemistry Review(s)	X			
EA/FONSI				X
Pharmacology Review(s)				X
Statistical Review(s)				
Microbiology Review(s)				X
Clinical Pharmacology Biopharmaceutics Review(s)				X
Bioequivalence Review(s)	X			
Administrative/ Correspondence Document(s)	X			

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APPROVAL LETTER

ANDA 74-962

Upsher-Smith Laboratories, Inc.
Attention: Mark B. Halvorsen, Pharm.D.
14905 23rd Avenue North
Minneapolis, MN 55447

MAR 31 1999

Dear Sir:

This is in reference to your abbreviated new drug application dated September 17, 1996, 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 February 12, and September 8, 1997; and March 12, 1999.

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® (Pentoxifylline) 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 deionized water at 37°C using USP 23 apparatus I (basket) at 100 rpm. The test product should meet the following "interim" dissolution specifications:

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,

199

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