

March 24, 1999

Andrx Pharmaceuticals, Inc.
Attention: Jacqueline Davis
4001 S.W. 47th Avenue
Ft. Lauderdale, Florida 33314

Dear Madam:

This is in reference to your abbreviated new drug application dated December 11, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Ketoprofen Extended-release Capsules, 100 mg, 150 mg and 200 mg.

Reference is also made to your amendments dated December 3, 1998; and January 20, February 1, and March 1, 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 Ketoprofen Extended-release Capsules, 100 mg, 150 mg, and 200 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Oruvail Extended-release Capsules, 100 mg, 150 mg, and 200 mg, respectively, of Wyeth Ayerst Research).

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

Time (hours)	Specification
1	
2	
4	
8	
18	

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

21 CFR 314.70 (c)(1) if there are no revisions to the "interim" specifications or when the final specifications are tighter than the "interim" specifications. In all other instances, the supplemental application 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.

Validation of the regulatory methods has not been completed. It is the policy of the Office not to withhold approval until the validation is complete. We acknowledge your commitment to satisfactorily resolve any deficiencies that may be identified.

Sincerely yours,

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