CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

74879

APPROVAL LETTER

DW

ANDA 74-879

DEC 10 1997

Elan Pharmaceutical Research Corporation
Attention: Sharon L. Hamm, Pharm.D.
1300 Gould Drive
Gainesville, GA 30504-3947

Dear Madam:

This is in reference to your abbreviated new drug application dated March 29, 1996, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Ketoprofen Extended-release Capsules, 200 mg.

Reference is also made to your amendments dated October 18, November 22, and December 18, 1996; and May 28, July 8, August 20, September 5, September 9, October 7, October 14, October 29, October 30, November 12 and November 13, and November 25, 1997.

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, 200 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Oruvail® Extended-release Capsules, 200 mg, of Wyeth Ayerst Research.

Your "interim" dissolution testing should be incorporated into the stability and quality control program using the same method stated in our October 7, 1997, correspondence. The "interim" dissolution test(s) and tolerances are:

The dissolution testing should be conducted in 900 mL of phosphate buffer, pH 7.2, at 37 C using USP 23 apparatus 2 (paddle) at 50 50 rpm. The test product should meet the following interim specifications:

Time (hr) *	Amount Dissolved
1	Not less than ___ % and not more than ___ %
2	Not less than ___ % and not more than ___ %
4	Not less than ___ % and not more than ___ %
8	Not less than ___ % and not more than ___ %
16	Not less than ___ %

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. 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.

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 which may be identified.

Sincerely yours,

Roger L. Williams, M.D.
Deputy Center Director for Pharmaceutical Science
Center for Drug Evaluation and Research