ANDA 75-299

November 3, 1999

Baxter Pharmaceutical Products, Inc.
Attention: Priya Jambhekar
95 Spring Street
New Providence, NJ 07974

Dear Madam:

This is in reference to your abbreviated new drug application dated December 29, 1997, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Ketorolac Tromethamine Injection USP, 15 mg/mL [15 mg (1 mL) single-dose syringes]; and 30 mg/mL [30 mg (1 mL) single-dose and 60 mg (2 mL) single-dose syringes].

Reference is also made to your amendments dated May 29, June 11, and June 30, 1998; and July 28 (2 submissions), July 29, August 26, October 22 and October 29, 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 Keterolac Tromethamine Injection USP, 15 mg/mL and 30 mg/mL, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Toradol**7** Injection, 15 mg/mL and 30 mg/mL, respectively, of Syntex Laboratories, Inc.).

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 that 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