75-665/S-001, S-002, S-003 February 5, 2001

TEVA Pharmaceuticals USA
Attention: Philip Erickson
1090 Horsham Road
PO Box 1090
North Wales, PA 19454

Dear Sir:

This is in reference to your supplemental new drug applications dated November 27, 2000, submitted under section 505(j) of the Federal Food, Drug, and Cosmetic Act, regarding your abbreviated new drug application for Etodolac Extended-Release Tablets, 400 mg, 500 mg, and 600 mg.

Reference is also made to the Tentative Approval letter issued by this office on July 31, 2000 for the 400 mg strength.

These supplemental applications provide for the final approval of the 400 mg strength and the following changes:

S-001: Updated release and finished product stability specifications;

S-002: Labeling

S-003: Alternate bottle vendor

We have completed the review of these supplemental abbreviated applications and have concluded that the 400 mg strength of the drug product is safe and effective for use as recommended in the submitted labeling. Accordingly, the supplemental applications are approved. The Division of Bioequivalence has determined your Etodolac Extended-Release Tablets, 400 mg to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Lodine® XL Tablets, 400 mg of Wyeth-Ayerst Laboratories Inc.). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

We remind you that you must comply with the requirements for an approved abbreviated application described 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.

The material submitted is being retained in our files.

Sincerely yours,

Gary Buehler
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research