ANDA 75-009/S-002, S-003, S-004, S-005, S-006

Prior Approval Supplements

DEC 28 1999

Teva Pharmaceuticals USA
Attention: Deborah A. Jaskot
1510 Delp Drive
P.O. Box 247
Kulpsville, PA 19443

Dear Madam:

This is in reference to your supplemental new drug applications dated September 18, 1998, submitted under section 505 (j) of the Federal Food, Drug and Cosmetic Act (ACT), regarding your abbreviated new drug application for Etodolac Tablets, 400 mg.

Reference is also made to your amendment dated May 14, 1999.

The supplemental applications submitted as "Prior Approval Supplements", provide for:

S-002: An additional tablet strength of 500 mg;

S-003: Updated labeling to incorporate the new Strength;

S-004: Packaging for the new strength;

S-005: Revised chemistry, manufacturing, and controls for the new strength; and

S-006: Expiration dating for the new strength.

We have completed the review of these supplemental applications and have concluded that the additional strength (500 mg) 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 Tablets, 500 mg, to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Lodine Tablets, 500 mg, of Wyeth Ayerst Laboratories, Inc.). Your dissolution testing should be incorporate into the stablility and quality control program using the same method proposed in your application.

We remind you that you must comply with the requirement for an approved abbreviated new drug application described in 21 CFR 314.80-81 and 314.98. The Office of Generic Drug 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 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 the 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,

/S/ 12/28/99

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