DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 74-056/S-021, S-022, S-023

Food and Drug Administration
Rockville MD 20857

JUL 19 2004

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

Dear Sir:

This is in reference to your supplemental new drug applications (S-021 and S-022) dated October 21, 2002 and (S-023) dated October 6, 2003, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), regarding your abbreviated new drug application for Atenolol Tablets USP, 50 mg and 100 mg.

Reference is also made to your amendment April 30, 2004.

The supplemental applications provide for:

S-021: An additional 25 mg tablet strength;

S-022: Updated labeling to provide for the new 25 mg strength; and

S-023: Dissolution data in support of the new 25 mg strength.

We have completed the review of these supplemental applications as amended, and have concluded that the new 25 mg strength of the drug product is safe and effective for use as recommended in the submitted labeling. Accordingly, these supplemental applications are approved. The Division of Bioequivalence has determined your Atenolol Tablets USP, 25 mg to be bioequivalent and therefore therapeutically equivalent, to the listed drug (Tenormin Tablets, 25 mg, of AstraZeneca LP. 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 new drug 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.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising, and Communications,
HFD-42
5600 Fishers Lane
Rockville, MD 20857

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,

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