DEPARTMENT OF HEALTH & HUMAN SERVICES

ANDA 76-416

Food and Drug Administration
Rockville MD 20857

SEP 29 2003

Caraco Pharmaceutical Laboratories, Ltd.
Attention: Susan Banks-Williams, Ph.D.
1150 Elijah McCoy Drive
Detroit, MI 48202

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated May 17, 2002, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act (Act), for Tizanidine Hydrochloride Tablets, 2 mg and 4 mg.

Reference is also made to your amendments dated October 24, 2002; and July 25, August 13, August 25, and September 23, 2003.

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 Tizanidine Hydrochloride Tablets, 2 mg (base) and 4 mg (base) to be bioequivalent and therapeutically equivalent to the listed drug (Zanaflex® Tablets, 2 mg (base) and 4 mg (base), respectively, of Elan Pharmaceuticals). Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your application.

Under Section 506A of the Act, 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 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 final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FDA 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 FDA 2253 at the time of their initial use.

The agency's field staff has not completed its validation of the regulatory methods. It is the policy of the Office to proceed with approval of your application while this process is ongoing. We acknowledge receipt of your commitment to cooperate with the agency to resolve satisfactorily any deficiencies related to the validation process that may be identified.

Sincerely yours,

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