DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18-017/S-037

Merck & Co., Inc.
Attention: Mr. Kenneth A. Kramer
Sumney Town Pike
P.O. Box 4, BLA-20
West Point, PA 19486

Dear : Mr. Kramer:

Please refer to your supplemental new drug application dated September 19, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Blocadren (timolol maleate) 5, 10 and 20 mg Tablets.

This "Changes Being Effected" supplemental new drug application provides for final printed labeling revised as follows:

1. The word, “anaphylaxis” has been added to the ADVERSE REACTIONS/Body as a whole subsection.

2. Under the HOW SUPPLIED section, the National Stock Numbers have been deleted and the corporate logo and signature have been updated.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the final printed label included in your September 19, 2001 submission. Accordingly, the supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call:

Ms. Zelda McDonald
Regulatory Health Project Manager
(301) 594-5333

Sincerely,

{See appended electronic signature page}

Douglas C. Throckmorton, M.D.
Acting Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Doug Throckmorton

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