CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-330 / S-017

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-330/S-017

Merck & Co., Inc.
Attention: Virginia G. Snyder
Manager, Regulatory Affairs
P.O. Box 4
Sumneytown Pike, BLA-20
West Point, PA 19486

Dear Ms. Snyder:

Please refer to your supplemental new drug application dated June 20, 2003, received June 23, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Timoptic XE (timolol maleate ophthalmic gel forming solution) 0.25%, 0.5%.

This "Changes Being Effected" supplemental new drug application provides for the addition of pH and osmolarity information to the DESCRIPTION section of the package insert labeling and a more complete description of the containers and fill sizes in the HOW SUPPLIED section of the package insert labeling.

We completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed submitted draft labeling (package insert submitted June 20, 2003).

The following revision should be made at the time of the next package insert labeling change:

> In the HOW SUPPLIED section, the words "color coded" should be changed to "light blue" in the description of the 0.25% strength container cap and to "yellow" in the description of the 0.5% strength container cap.

We recommend changing the cap color of the 0.25% strength container to yellow for consistency with other topical beta-blocker ophthalmic products.

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-330/S-017." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

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

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Michael Puglisi, Regulatory Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Linda L. Ng, Ph.D.
Chemistry Team Leader for the
Division of Anti-Inflammatory, Analgesic
and Ophthalmic Drug Products, HFD-550
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

Enclosure

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

/s/

Linda Ng
12/22/03 04:42:55 PM