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APPLICATION NUMBER:

18-086 / S-060

APPROVABLE LETTER (S)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18-086/S-060

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 11, 2002, received June 12, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Timoptic (timolol maleate ophthalmic solution) 0.25%/0.5%.

We acknowledge receipt of your submission dated November 22, 2002.

This "Changes Being Effected" supplemental new drug application provides for the revision of the drug product specification.

We have completed the review of this application, as amended, and it is approvable. Before this application may be approved, however, it will be necessary for you to address the following:

Please submit package insert labeling with the revisions proposed in this supplement.

Within 10 days after the date of this letter, you are required to amend the supplemental application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. In the absence of any such action FDA may proceed to withdraw the application.

Under 21 CFR 314.102(d) of the new drug regulations, you may request an informal meeting or telephone conference with this division to discuss what further steps need to be taken before the application may be approved.

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If you have any questions, call Michael Puglisi, 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

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/s/

Linda Ng
12/11/02 03:12:15 PM