CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

18-086 / S-060

ADMINISTRATIVE DOCUMENTS AND CORRESPONDENCE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 18-086/S-060

CBE-0 SUPPLEMENT

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:

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Timoptic (timolol maleate ophthalmic solution) 0.25%, 0.5%

NDA Number: 18-086

Supplement Number: S-060

Date of Supplement: June 11, 2002

Date of Receipt: June 12, 2002

This supplemental application, submitted as a "Supplement - Changes Being Effected" supplement, proposes the addition of a new release specification for osmolarity of the drug product.

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on August 11, 2002, in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be December 12, 2002.

Please cite the application number listed above at the top of the first page of any communications concerning this application. All communications concerning this supplemental application should be

addressed as follows:

U.S. Postal Service:
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products, HFD-550
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products, HFD-550
9201 Corporate Boulevard
Rockville, Maryland 20850-3202

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

Sincerely,

{See appended electronic signature page}

Carmen DeBellas, R.Ph.
Chief, Project Management Staff
Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research

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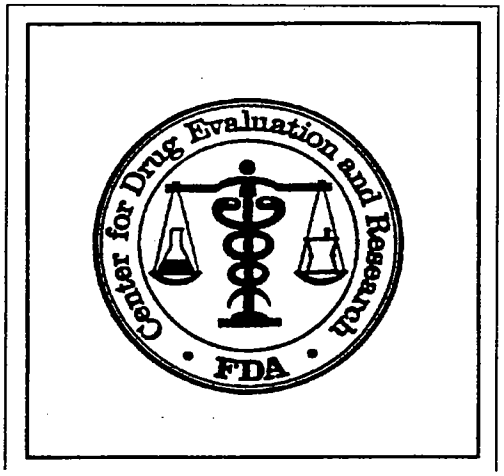
/s/

Michael Puglisi
6/27/02 02:46:56 PM
for Carmen DeBellas

FACSIMILE TRANSMISSION
RECORD



From: Allan Fenselau, Ph.D.

Division of Anti-Inflammatory, Analgesic
and Ophthalmic Drug Products, HFD-550

Phone 301-827-2050
Fax 301-827-2531

Date: October 29, 2002 .

To:

Name Virginia Snyder
Company Merck & Co.
City _____ State ____
Phone # 484-344-7984

FAX # 484-344-2516

Number of Pages (INCLUDING COVER PAGE) 2

Please telephone (301) 827-2040 IMMEDIATELY if re-transmission is necessary.

Dear Ms. Snyder, **NDA 18-086/SCS-060**

Please respond to the following request for information as soon as possible. A response by 08-NOV-02 would be greatly appreciated. Please let me know if this deadline cannot be met. If you have any questions or need clarification, please give me a call.

Allan Fenselau, Ph.D.
Review Chemist

NDA Number: 18-086/S-060 **Applicant: Merck & Co.**
Drug Name: TIMOPTIC Ophthalmic Solution **29-OCT-02**

These comments are being provided to you prior to completion of our review of the application to give you preliminary notice of issues that have been identified. Per the user fee reauthorization agreements, these comments do not reflect a final decision on the information reviewed and should not be construed to do so. These comments are preliminary and are subject to change as the review of your application is finalized. In addition, we may identify other information that must be provided prior to approval of this application. If you choose to respond to the issues raised in this letter during this review cycle, depending on the timing of your response, as per the user fee reauthorization agreements, we may or may not be able to consider your response prior to taking an action on your application during this review cycle.

NOTE: If your response can be found in the contents of your submission, just cite those sections of the submission that are relevant to the issue under consideration. Otherwise, please provide the appropriate information as an amendment to the submission.

Chemist's Concerns

1. [redacted]

2. [redacted]

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/s/

Allan Fenselau
10/29/02 08:10:07 AM
CHEMIST

Linda Ng
10/29/02 09:18:14 AM
CHEMIST
No action needed by PM