



NDA 20-067/S-005

Hoffmann-La Roche Inc.
Attention: Lynn DeVenezia-Tobias
Program Manager
Drug Regulatory Affairs
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Ms De Venezia-Tobias:

Please refer to your supplemental new drug application dated March 11, 1998, received March 12, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for EC- Naprosyn (naproxen) Delayed-Release Tablets.

This supplemental new drug application provides for revisions to package insert text where the 1500-mg dose is mentioned.

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 submitted labeling (package insert submitted March 11, 1998).

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 ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-067/S-005." Approval of this submission by FDA is not required before the labeling is used.

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, HF-2
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 Barbara Gould, Regulatory Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Lee S. Simon, M.D.
Division Director
Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products,
HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
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/s/

Lee Simon

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