DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-581/S-105, NDA 18-164/S-055
NDA 18-965/S-013, NDA 20-067/S-010

Hoffman- La Roche Inc
340 Kingsland Street
Nutley, NJ 07110

Attention: Barbara Taylor, Ph.D.
Group Director, Regulatory Affairs

Dear Dr. Taylor:

Please refer to your supplemental new drug applications dated April 12, 2005, received April 15, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following products:

NDA #	Supplement #	Drug
17-581	S-105	Naprosyn (naproxen tablets)
18-164	S-055	Anaprox /Anaprox DS (naproxen sodium tablets)
18-965	S-013	Naprosyn (naproxen suspension)
20-067	S-010	EC Naprosyn (naproxen delayed-release tablets)

These supplemental new drug applications provides for thee revisions to the **DESCRIPTION, CLINICAL PHARMACOLOGY, PRECAUTIONS, ADVERSE REACTIONS, DOSAGE AND ADMINISTRATION AND HOW SUPPLIED** sections of the package insert.

We have completed our review of these applications and they are 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, and include the revisions indicated, to the enclosed labeling text for the package insert. These revisions are terms of the approval of this application.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDAs 17-581/S-105, 18-164/S-055, 18-965/S-013 and 20-067/S-010."** Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about these drug products (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
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Kimberly Compton, Regulatory Project Manager, at (301) 796-1191.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, M.D.
Director
Division of Anesthesia, Analgesia and Rheumatology Products
Office of Drug Evaluation II
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/

Sharon Hertz
3/10/2006 03:59:36 PM
Signing for Bob Rappaport, M.D.