DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-581/S-108, NDA 18-164/S-058
NDA 18-965/S-016, NDA 20-067/S-014

Hoffmann-La Roche Inc.
340 Kingsland Street
Nutley, New Jersey 07110-1199

Attention: Lynn DeVenezia-Tobias
Program Manger, Drug Regulatory Affairs

Dear Ms. DeVenezia-Tobias:

Please refer to your supplemental new drug applications dated March 5, 2007, received March 7, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following products:

NDA #	Supplement #	Drug
17-581	S-108	Naprosyn (naproxen tablets)
18-164	S-058	Anaprox/Anaprox DS (naproxen sodium tablets)
18-965	S-016	Naprosyn (naproxen suspension)
20-067	S-014	EC-Naprosyn (naproxen delayed-release tablets)

These supplemental new drug applications propose to add safety information to the **WARNINGS**, **PRECAUTIONS**, **ADVERSE REACTIONS** and **OVERDOSEAGE** sections of the package insert.

We have completed our review of these applications, as amended. These applications 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 to the enclosed labeling text for the Package Insert and Medication Guide.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate these submissions "SPL for approved supplement NDA 17-581/S-108, 18-164/S-058, 18-965/S-016, and 20-067/S-014." Approval of these submissions 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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Sharon Turner-Rinehardt, Regulatory Project Manager, at (301) 796-2254.

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: Package Insert
Medication Guide

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
9/20/2007 01:00:15 PM
signing for Bob Rappaport, M.D.