



NDA 17-581/S-107, NDA 18-164/S-057
NDA 18-965/S-015, NDA 20-067/S-013

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 February 5, 2007, received February 6, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following products:

NDA #	Supplement #	Drug
17-581	S-107	Naprosyn (naproxen tablets)
18-164	S-057	Anaprox/Anaprox DS (naproxen sodium tablets)
18-965	S-015	Naprosyn (naproxen suspension)
20-067	S-013	EC-Naprosyn (naproxen delayed-release tablets)

These “Changes Being Effected” supplemental new drug applications provide for revisions to the NSAID Medication Guide table “NSAID medicines that need a prescription” to include the class labeling change for all NSAID medications.

Please 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 these submissions "**FPL for approved supplement NDA 17-581/S-107, 18-164/S-057, 18-965/S-015, and 20-067/S-013.**" 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

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

Bob Rappaport
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