DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-581/S-099 & 100
NDA 18-164/S-050 & 051
NDA 18-965/S-009 & 010
NDA 20-067/S-004 & 006

Roche Palo Alto LLC
Attention: Lisa A. Aronson, RPh, MS
Program Manager, Drug Regulatory Affairs
c/o Hoffmann-La Roche, Inc.
340 Kingsland Street
Nutley, NJ 07110

Dear Ms. Aaronson:

Please refer to your supplemental new drug applications dated May 06, 2004, received May 10, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

NDA Number	Supplement Number	Drug Name
17-581	S-099 & 100	Naprosyn® (naproxen) Tablets 250mg, 375 mg, 500 mg
18-164	S-050 & 051	Anaprox/Anaprox DS (naproxen sodium) Tablets 275 mg, 500 mg
18-965	S-009 & 010	Naprosyn (naproxen) Suspension 125mg/5mL
20-067	S-004 & 006	EC-Naprosyn (naproxen) Delayed Release Tablets 375 mg, 500 mg

Your submission of May 06, 2004 constituted a complete response to our May 06, 2003 action letter.

These supplemental new drug applications provide for updates to make the package insert consistent with the NSAID Class Label and update the Geriatric Patients section under Special Populations in the CLINICAL PHARMACOLOGY section.

We 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.

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999) and *Providing Regulatory Submissions in*

submitted in *pdf* format. To assist in our review, we request that labeling also be submitted in MS Word format. If formatted copies of all labeling pieces (i.e., package insert, patient package insert, container labels, and carton labels) are submitted electronically, labeling does not need to be submitted in paper.

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) 827-2506.

Sincerely,

{See appended electronic signature page}

Sharon Hertz, M.D.
Deputy Director
Division of Anti-Inflammatory, Analgesic, &
Ophthalmic Drug Products
Office of Drug Evaluation V
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
11/10/04 04:51:17 PM