DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-581/S-098
NDA 18-965/S-007
NDA 18-164/S-049

Syntex Development Research
Division of Syntex (U.S.A.) Inc.
Attention: Ms. Karen Hamme
3401 Hillview Avenue
Palo Alto, California 94303

Dear Ms. Hamme:

Please refer to your supplemental new drug applications dated November 29, 1994, received December 1, 1994 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Naprosyn® (naproxen), NDA 17-851; Naprosyn® (naproxen) Suspension, NDA 18-965 and Anaprox (naproxen sodium), NDA 18-164.

These supplemental new drug applications provide for the addition of new product information to existing labels

We completed our review of these applications. 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 submitted labeling dated November 29, 1994.

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, these submissions should be designated "FPL for approved supplement NDA 17-581/098 AND NDA 18-965/S-007." 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, 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.
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 this page is the manifestation of the electronic signature.

/s/

Lee Simon

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