



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 13-416/S-021

Riker Laboratories, Inc.
Attention: Jeanne M. Fox
Regulatory Coordinator
270-3A 3M Center
St. Paul, Minnesota 55144

Dear Ms. Fox:

Please refer to your supplemental new drug application dated February 14, 1986, received February 14, 1986, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Norgesic/Norgesic Forte Tablets.

We acknowledge receipt of your submission dated October 10, 1996.

We have completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

Please submit a new supplemental application that incorporates the NSAID format into the labeling. An NSAID template is attached to this correspondence for your reference.

Additional sections that should be incorporated into the new supplemental application label include, but are not necessarily limited, to the following: pharmacodynamics/pharmacokinetics, special populations, expansion of the **WARNINGS SECTION** (to include anaphylactoid reactions for example), and additional information available since the last update of the label concerning **PRECAUTIONS AND ADVERSE REACTIONS/DRUG INTERACTIONS**.

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, this submission should be designated "FPL for approved supplement NDA 13-416/S-021." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division/ the Division of Anti-Inflammatory, Analgesic, and Ophthalmologic Drug Products, HFD-550, and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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 Nancy Halonen, 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

Enclosure : NSAIDS Template

**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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