DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-341/S-002

Pharmacia Corporation
Attention: Peter F. East
Associate Director, Regulatory Affairs
4901Searle Parkway
Skokie, IL 60077

Dear Mr. East:

Please refer to your supplemental new drug application dated October 24, 2002, received October 25, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for BEXTRA (valdecoxib sodium) tablets, 10 mg and 20 mg.

We acknowledge receipt of your submission dated October 25, 2002.

This "Changes Being Effected" supplemental new drug application provides for the following label changes:

The addition of a new contraindication sentence for patients with a history of allergic reactions to sulfonamides, which reads as, follows:

" BEXTRA should not be given to patients who have demonstrated allergic-type reactions to sulfonamides."

The addition of a new **WARNINGS** section:

Serious Skin Reactions
Serious skin reactions, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis, have been reported through postmarketing surveillance in patients receiving BEXTRA (see ADVERSE REACTIONS-Postmarketing Experience).
As these reactions can become life threatening, BEXTRA should be discontinued at the first appearance of kin rash or any other sign of hypersensitivity.

The addition of a new sentence to the Warnings-**Anaphylactoid Reactions** section which reads as follows:

> "In postmarketing experience, cases of hypersensitivity reactions (anaphylactoid reactions and angioedema) have been reported in patients receiving BEXTRA (see ADVERSE REACTIONS-Postmarketing Experience). These cases have occurred in patients with and without a history of allergic-type reactions to sulfonamides (see CONTRAINDICATIONS)."

The addition of a new paragraph in the **ADVERSE REACTIONS** section:

Postmarketing Experience
The following reactions have been identified during postmarketing use of BEXTRA. These reactions have been chosen for inclusion either due to their seriousness, reporting frequency, possible causal relationship to BEXTRA, or a combination of these factors.
Because these reactions were reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to drug exposure.
General: Hypersensitivity reactions (including anaphylactic reactions and angioedema)
Skin and appendages: Erythema multiforme, exfoliative dermatitis, Stevens-Johnson syndrome, toxic epidermal necrolysis

We completed our review of this application as amended. This application is 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 package insert submitted October 25, 2002, and must be formatted in accordance with the requirements of 21 CFR 201.66.

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 21-341/S-002. " 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 the Division of Anti-Inflammatory, Analgesic, and Ophthalmic Drug Products 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) 827-2019.

Sincerely,

{See appended electronic signature page}

Lawrence Goldkind, M.D.
Deputy 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/

Lawrence Goldkind

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