DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-607/S-010

Pfizer, Inc.
235 East 42nd Street
New York, New York 10017-5755

Attention: Amanda Radola
Manager
World Wide Regulatory Affairs and Quality Assurance

Dear Ms. Radola,

Please refer to your supplemental new drug application dated February 26, 2007, received February 27, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Arthrotec (diclofenac sodium and misoprostol) tablets.

This "Changes Being Effected" supplemental new drug application provides a response to our January 10, 2007 supplement request letter recommending the following changes in your label:

- Add an * next to the word Vicoprofen

- Add the following footnote under the table: "*Vicoprofen contains the same dose of ibuprofen as over-the counter (OTC) NSAIDs, and is usually used for less than 10 days to treat pain. The OTC NSAID label warns that long term continuous use may increase the risk of heart attack or stroke"

We completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text (see attachment).

We note that you have submitted content of labeling in structured product labeling (SPL) format that is identical to the enclosed labeling text. We will transmit it to the National Library of Medicine for posting on the DailyMed website after verification.

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 Giuseppe Randazzo, Regulatory Project Manager, at (301) 796-0980.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., MPH
Deputy Director
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure (label)

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Joyce Korvick

8/24/2007 11:52:18 AM