DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-607/S-009

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

Attention: Pritpal Nijjar
Regulatory Manager
Worldwide Regulatory Strategy

Dear Pritpal Nijjar:

Please refer to your supplemental new drug application dated July 22, 2005, received July 25, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Arthrotec (diclofenac sodium)

We acknowledge receipt of your submission dated August 19, 2005.

This "Changes Being Effected in 30 days" supplemental new drug application was submitted in response to the Agency's letter dated June 14, 2005, requiring class labeling language for all non-selective non-steroidal anti-inflammatory drugs (NSAIDS), to include a boxed warning to address possible cardiovascular risks as well as known gastrointestinal risks, revised **CONTRAINDICATIONS, WARNINGS** and **PRECAUTIONS** sections of the package insert (PI), and a **MedGuide** for NSAIDS.

We have 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.

The final printed labeling (FPL) must be identical, and include the revisions indicated, to the enclosed labeling text for the package insert and the MedGuide. The revisions were agreed upon during a December 1, 2005 teleconference. These revisions are terms of the approval of this application.

MedGuides are required to be reprinted at the end of the PI [201.57(f)(2)] and are required to be distributed as a separate sheet to the patient. Products that are required to have a MedGuide cannot also have a separate patient information leaflet. The MedGuide would be the only allowable patient labeling. A required Class MedGuide may be expanded to include product-specific information.

The Class MedGuide is included in your label for the action. We recommend additional drug specific changes be made to this MedGuide. The will also be subject of a future supplement request letter.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-607/S-009**." Approval of this submission 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
Food and Drug Administration
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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, Consumer Safety Officer, at (301) 796 0980.

Sincerely,

{See appended electronic signature page}

Brian E. Harvey, M.D. Ph.D.
Director
Division of Gastroenterology Products
Office of Drug Evaluation III
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/

Joyce Korvick
1/25/2006 04:52:31 PM
for Dr. Brian E Harvey