DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-607/S-014

G.D. Searle LLC
235 East 42nd Street
New York, NY 10017

Attention: Tricia Douglas
Pfizer, Inc.
Manager, World Wide Regulatory Strategy

Dear Ms. Douglas:

Please refer to your supplemental new drug application dated November 11, 2008, received November 11, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Arthrotec (diclofenac sodium and misoprostol) Tablets.

Reference is also made to an FDA letter dated October 3, 2008, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the Arthrotec labeling to address the risk of elevations in liver enzymes associated with the use of diclofenac-containing drug products.

Your supplemental new drug application provides for revisions to the labeling for Arthrotec, consistent with our October 3, 2008, letter and email correspondence between you and FDA dated February 6, 9, 10, and 11, 2009, in which agreement was reached on these safety labeling changes.

We also acknowledge receipt of your submissions dated December 3 and 15, 2008; and February 19, 2009.

We have 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.

Within 21 days of the date of this letter, amend any pending CBE applications for this NDA with content of labeling in structured product labeling (SPL) format to include the changes approved in this application.

Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

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
Suite 12B05
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 Jagjit Grewal, Regulatory Project Manager, at (301) 796-0846.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Package Insert

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

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