DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-776/S-002

G.D. Searle LLC
c/oPfizer Inc.
235 East 42nd Street
New York, NY 100017

Attention: Robert B. Clark
Vice President, US Regulatory Strategy

Dear Mr. Clark:

Please refer to your supplemental new drug application dated February 26, 2007, received February 27, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Daypro Alta™ (oxaprozin potassium) 600 mg tablets.

This "Changes Being Effected" supplemental new drug application provides for changes to the NSAID Medication Guide as requested in our January 18, 2007, letter.

We have completed our review of this supplemental new drug application and it is approved, effective on the date of this letter, for use as recommended in the enclosed labeling (text for package insert and Medication Guide) submitted on February 26, 2007. We note that you have submitted content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format that is identical to the enclosed labeling.

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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Kathleen Davies, Regulatory Project Manager, at (301) 796-2205.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, MD
Director
Division of Anesthesia, Analgesia
And Rheumatology Products
Office of Drug Evaluation II
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/

Sharon Hertz
7/5/2007 03:22:19 PM
signing for Bob Rappaport, M.D.