



NDA 20-998/S-022

G.D. Searle LLC  
c/o Pfizer Inc.  
235 East 42<sup>nd</sup> Street  
New York, NY 10017

Attention: Robert B. Clark  
Vice President, U.S. Regulatory, Pfizer Inc.  
Acting as Agent for G.D. Searle LLC

Dear Mr. Clark:

Please refer to your supplemental new drug application dated March 14, 2007, received March 15, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for CELEBREX® (celecoxib) capsules.

This “Changes Being Effectuated” supplemental new drug application is submitted in response to the Agency’s January 5, 2007, letter requesting revision to the CELEBREX® Medication Guide to comply with the class-labeling changes for the NSAID Medication Guide.

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 FPL submitted on March 14, 2007.

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

If you have any questions, call Lauren Tornetta, Regulatory Project Manager, at (301) 796-2246.

Sincerely,

*{See appended electronic signature page}*

Bob Rappaport, M.D.  
Director  
Division of Anesthesia, Analgesia  
and Rheumatology Products  
Office of Drug Evaluation II  
Center for Drug Education and Research

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/s/

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Bob Rappaport  
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