

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-988 /S-014

APPROVAL LETTER



NDA 20-998/S-014

G.D.Searle & Co.
Attention: Eva Essig, Ph.D.
Director, Global Regulatory Affairs
4901 Searle Parkway,
Skokie, IL 60077

Dear Dr. Essig:

Please refer to your supplemental new drug application dated March 20, 2002, received March 21, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Celebrex™, (Celecoxib) Capsules, 100 and 200 mg.

This "Changes Being Effected in 30 days" supplemental new drug application provides for an alternate packaging configuration for blisters consisting of _____

We have completed the review of this supplemental application, and it is approved.

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 Jane Dean, Regulatory Project Health Coordinator, at 301-827-2090.

Sincerely,

{See appended electronic signature page}

John Smith, Ph.D.
Chemistry Team Leader for the
Division of Anti-Inflammatory, Analgesic and
Ophthalmic Drug Products, (HFD-550)
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

John Smith

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