

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-988 /S-014

ADMINISTRATIVE DOCUMENTS
AND
CORRESPONDENCE



NDA 20-998/S-014

CBE-30 SUPPLEMENT

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

Dear Dr. Essig,

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Celebrex™ (celecoxib)

NDA Number: 20-998

Supplement number: S-014

Date of supplement: March 20, 2002

Date of receipt: March 21, 2002

This supplemental application was submitted as a "Supplement - Changes Being Effected in 30 days." The appropriateness of reporting the proposed change(s) as changes being effected in 30 days is under review.

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on 20 May 2002, in accordance with 21 CFR 314.101(a).

All communications concerning this supplement should be addressed as follows:

U.S. Postal Service:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products, HFD-550
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anti-Inflammatory, Analgesic and Ophthalmic Drug Products, HFD-550
9201 Corporate Boulevard
Rockville, Maryland 20850

If you have any question, please call Ms. Jane A. Dean, RN, MSN, Regulatory Health Project Manager,
at (301) 827-2090.

Sincerely yours,

Carmen DeBellas, R. Ph.
Chief, Project Management Staff
Division of Anti-Inflammatory, Analgesic
and Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
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/s/

Carmen DeBellas
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