CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-998 / S-001

Trade Name: Celebrex

Generic Name: (celecoxib)

Sponsor: GD Searle

Approval Date: August 13, 1999

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APPLICATION NUMBER:

20-998 / S-001

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Reviews / Information Included in this NDA Review.	
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Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
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APPLICATION NUMBER:

20-998 / S-004

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-998/S-001

AUG 13 1999

G.D.Searle & Co.
Attention: Roger Nosal
Director, Regulatory Affairs
4901 Searle Parkway
Skokie, IL 60077

Dear Mr. Nosal::

Please refer to your supplemental new drug application dated April 19, 1999, received April 20, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Celebrex™ (celecoxib capsules) Capsules, 100 mg and 200 mg.

This supplemental new drug application provides for 500-count and 1000-count high density _____ for the drug product.

We have completed the review of this supplemental application and it is approved. Please submit the revised labeling in the next Annual Report as per 21 CFR 314.70(d)(2).

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, contact Anthony M. Zeccola, Chief, Project Management Staff, at (301) 827-2090.

Sincerely,

Hasmukh B. Patel 8/13/99

Hasmukh B. Patel, Ph.D.
Chemistry Team Leader, DNDC III 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

cc:
Archival NDA 20-998
HFD-550/Div. Files
HFD-550/A.Zeccola
HFD-550/V.Bhavnagri/H.Patel
HFD-094/DDMS (with labeling)
HFD-830/DNDC III Div. Dir./C-w. Chen
DISTRICT OFFICE

Drafted by: /August 13, 1999
Initialed by:
final:
filename: 20998S01

APPROVAL (AP)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-998 / S-001

CHEMISTRY REVIEW(S)

AUG 13 1999

Chemistry Review #1	1. Division HFD-550	2. NDA Number 20-998
3. Name and Address of Applicant G.D. Searle and Co. 4901 Searle Parkway Skokie, IL 60077	**4. Supplement Number:** SCP 001 **Letter Date:** 4/19/99 **Stamp Date:** 4/20/99 **Due Date :** 8/20/99	
5. Name of Drug Celebrex™ Tablets	**6. Nonproprietary Name** Celecoxib	
7. Supplement Provides for: Larger bottle sizes		**8. Amendment(s)** None
9. Pharmacological Category To treat acute and chronic pain associated with OA and RA	**10. How Dispensed** Rx	**11. Related Documents**
12. Dosage Form Capsules	**13. Potency(ies)** 100 and 200 mg	
14. Chemical Name and Structure See NDA Reviews		
15. Comments The company wishes to package 500 capsules in 500 cc and 1,000 capsules in 750 cc [redacted]. The company has provided information for both and their respective caps. The cover letter states that the materials of construction for the new packages are identical to those approved in the NDA. The company has provided 3 months of stability data for 1,000 capsules/750 cc bottle, thus effectively bracketing the 500 capsules in the 500 cc bottle configuration between the 1,000 and 100 capsules packaging configurations (see attached notes).		
16. Conclusions and Recommendations The applicant has demonstrated that the drug product is stable in the larger container/closure systems. It is recommended that the supplement be approved, and a two year shelf life be granted. It is also recommended that the company be reminded to post the revised labeling to the next Annual Report.		
17. Name	**Signature**	**Date**
Vispi P. Bhavnagri, Ph.D., Review Chemist	V. P. Bhavnagri	8/12/99
Concurrence Hasmukh Patel, Ph.D., Team Leader	Hasmukh A Patel	8/13/99

cc:
NDA 20-998
HFD-550/Division File
HFD-550/V.Bhavnagri
HFD-550/A.Zeccola
HFD-830/Cw.Chen
APPROVE

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