CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

20-998 / S-004

Trade Name: Celebrex

Generic Name: (celecoxib)

Sponsor: GD Searle

Approval Date: February 17, 2000

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-998 / S-004

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Reviews / Information Included in this NDA Review.	
Approval Letter	X
Approvable Letter	
Final Printed Labeling	
Medical Review(s)	
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EA/FONSI	
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/ Biopharmaceutics Review(s)	
Administrative and Correspondence Document(s)	X

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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-004

FEB 17 2000

G.D. Searle
4901 Searle Parkway
Skokie, Illinois 60077

Attention: Roger Nosal
Director Regulatory Affairs
Chemistry, Manufacturing & Controls

Dear Mr. Nosal:

Please refer to your supplemental new drug application dated October 7, 1999, received October 8, 1999, 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" supplemental new drug application provides for a new drug product packaging site.

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 Leslie Vaccari, Project Manager, at (301) 827-2538.

Sincerely,

Mona Zarifa 2/17/00

Mona Zarifa, Ph.D.
Acting Chemisry 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/L.Vaccari
HFD-550/V Bhavnagri VOB 2/17/00
HFD-550/MZarifa
HFD-095/DDMS-IMT
HFD-830/DNDC Division Director
DISTRICT OFFICE

Drafted by: LAV/February 17, 2000 LAV 2-17-00

Initialed by: Vbhavnagri/ VOB 2/17/00

final:
filename:20-998/S-004

APPROVAL (AP)

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-998 / S-004

CHEMISTRY REVIEW(S)

FEB 2 2000

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:** SCM 004 **Letter Date:** 10/7/99 **Stamp Date:** 10/8/99 **Due Date :** 2/8/00	
5. Name of Drug Celebrex™ Capsules	**6. Nonproprietary Name** Celecoxib	
7. Supplement Provides for: CBE Packaging Site Change		**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 This is a CBE supplement. For reviewer's notes see attachment.		
16. Conclusions and Recommendations It is recommended that this supplement be approved.		
17. Name Vispi P. Bhavnagri, Ph.D., Review Chemist	**Signature** Vispi P. Bhavnagri	**Date** 2/1/00
Concurrence Mona Zarifa, Ph.D., Acting Team Leader	Mona Zarifa	2/2/00

cc:
NDA 20-998
HFD-550/Division File
HFD-550/V.Bhavnagri
HFD-550/SCook
HFD-550/M.Zarifa
HFD-830/Cw.Chen
APPROVE

Doc ID: a:\review\suppli\20998_SCM_04.Doc (Disk # 11)

WITHHOLD 2 PAGE(S)

B4 Chemistry Review

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20-998 / S-004

ADMINISTRATIVE DOCUMENTS AND CORRESPONDENCE

41.1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-998/S-004

OCT 18 1999

G. D. Searle & Co.
4901 Searle Parkway
Skokie, IL 60077

Attention: Roger Nosal
Director-CMC, Worldwide Regulatory Affairs

Dear Mr. Nosal:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Celebrex™ (celecoxib) 100 and 200 mg Capsule

NDA Number: 20-998

Supplement Number: S-004

Date of Supplement: October 7. 1999

Date of Receipt: October 8, 1999

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on December 7, 1999 in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Food and Drug Administration
Division of Anti-Inflammatory, Analgesic and
Ophthalmic Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research
Attention: Document Control Room
5600 Fishers Lane
Rockville, MD 20857

Sincerely,

Constance Lin MD 10/14/99

for Anthony M. Zeccola
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

cc:
Original NDA 20-998/S-004
HFD-550/Div. Files
HFD-550/CSO/Lewin C.

SUPPLEMENT ACKNOWLEDGEMENT

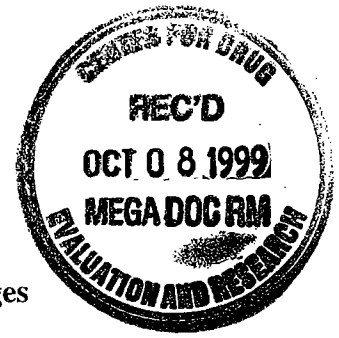
SEARLE ORIGINAL

October 7, 1999

NDA NO. 20-998 REF NO. 004
NDA SUPPL FOR SCM

SEARLE
4901 SEARLE PARKWAY
SKOKIE, ILLINOIS 60077
PHONE (847) 982-7000
FAX (847) 982-4701

Karen Midthun, M. D., Acting Director
Division of Anti-Inflammatory, Analgesic and
Ophthalmologic Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research (HFD-550)
9201 Corporate Boulevard
Rockville, MD 20850
Attn: Anthony Zaccola
Vispi Bhavnagri, Ph. D.



RE: Supplement with Changes Being Effected (CBE)
NDA 20-998
Celebrex™ (celecoxib)

Dear Dr. Midthun:

Reference is made to Searle's approved New Drug Application, NDA 20-998, for Celebrex™ (celecoxib). In accordance with FDA provisions for submission of a '[1] the enclosed registration information provides for a supplement with changes being effected (CBE) to NDA 20-998 to introduce the following new drug product packaging site:

[ ]

The following documents are enclosed in support of this supplement:

Document Title:
Document No.:
Document Date: 1 Oct 1999
Replaces document no.: dated: 29 May 1998.

[1] Memorandum from Roger L. Williams, M. D. to All NDA, ANDA and AADA Holders February, 1997.

Searle certifies that packaging operations at the [redacted] conform to those registered in NDA 20-998. In addition, Searle agrees to place the first production batch of Celebrex™ packaged at this site on long-term stability in accordance with the Stability Commitment provided in NDA 20-998 and submit the resulting data in the Annual Report.

If you have questions or comments please contact me directly.

Kind regards,

Roger Nosal
Director
Regulatory Affairs - Chemistry, Manufacturing & Controls