

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-988 /S-014

CHEMISTRY REVIEW(S)

Chemistry Review #1	1. Division HFD-550	2. NDA Number 20-998
3. Name and Address of Applicant G.D.Searle & Co. 4901 Searle Parkway, Skokie, IL 60077	4. Supplement Number: SCP 014 Letter Date: 3/20/02 Stamp Date: 3/21/02 Due Date : 9/21/02	
5. Name of Drug Celebrex™ Capsules	6. Nonproprietary Name Celecoxib	
7. Supplement Provides for: An alternate packaging configuration for blisters consisting of <hr/>		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 NC Dated 2/8/2001 NDA 21-156/SCP 002
12. Dosage Form Capsules	13. Potency(ies) 100 mg and 200 mg (OA and RA) & 400 mg (FAP)	
14. Chemical Name and Structure See USAN		
15. Comments This is a CBE 30 supplement. <hr/> 21-156/S002.		
16. Conclusions and Recommendations The information provided is adequate. Recommend approval of supplement <hr/>		
17. Name Vispi P. Bhavnagri, Ph.D., Review Chemist	Signature	Date
Concurrence John L Smith, Ph. D., Chemistry Team Leader		

APPROVE

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By

Chemistry Review

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/s/

Vispi Bhavnagri
9/16/02 09:27:15 AM
CHEMIST

John Smith
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