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APPLICATION NUMBER:

20-998/S-010

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 Pakway, Skokie, IL 60077	4. Supplement Number: SE1-010 Letter Date: 12/18/00 Stamp Date: 12/19/00 Due Date : 10/19/01	
5. Name of Drug Celebrex™ Capsules	6. Nonproprietary Name Celecoxib	
7. Supplement Provides for: An additional indication for management of pain in adults and for the treatment of dysmennorhea	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 None
12. Dosage Form Capsules	13. Potency(ies) 100 mg and 200 mg	
14. Chemical Name and Structure See USAN		
15. Comments This is an efficacy supplement. The NDA holder has asked for a categorical exclusion because the total amount of the DS that would required, including the amount for these two additional indications, would still be within the projections made in the original EA. The applicant has also certified that to the best of its knowledge the information provided in this application, for a categorical exclusion is true, accurate and complete.		
16. Conclusions and Recommendations It is recommended that the supplement be approved.		
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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/s/

Vispi Bhavnagri
8/22/01 10:03:42 AM
CHEMIST

John Smith
8/22/01 10:08:08 AM
CHEMIST