

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

20-988 /S-013

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: SCS 013 Letter Date 12/12/01 Stamp Date: 12/13/01 Due Date : 4/13/2002	
5. Name of Drug Celebrex™ Capsules	6. Nonproprietary Name Celecoxib	
7. Supplement Provides for: Manufacture of a 400 mg capsule strength		8. Amendment(s) BL Dated 1/18/02 BC Dated 2/7/02 BL Dated 4/5/02
9. Pharmacological Category To treat acute and chronic pain associated with OA and RA	10. How Dispensed Rx	11. Related Documents NDA 21156/ S 001 and S 002
12. Dosage Form Capsules	13. Potency(ies) 400 mg	
14. Chemical Name and Structure See USAN		
15. Comments This is a PA supplement. Searle wishes to manufacture a 400 mg. strength capsule so that instead of administering the approved dose of two 200 mg. capsules a single 400 mg capsule can be administered for FAP. NDA 21-156 was submitted to and approved by HFD 180 for the FAP indication. Since the 400 mg strength capsule will be used for FAP, it was decided between HFD 550 and HFD 180, that this change (submitted in S/001 and S/002 to NDA 21-156) would be reviewed by HFD 180. The HFD 550 chemistry reviewer would make reference to the HFD 180 review.		
16. Conclusions and Recommendations HFD 180 has four deficiencies that need to be addressed (see attachment). It is recommended that HFD 550 also make supplement 013 to NDA 20-998 approvable pending satisfactory resolution of these four deficiencies.		
17. Name Vispi P. Bhavnagri, Ph.D., Review Chemist	Signature	
Concurrence John Smith, Ph.D., Chemistry Team Leader		

APPROVABLE

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Chemistry Review 1a

Chemistry Review #2	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: SCS 013 Letter Date 4/26/02 Stamp Date: 4/29/02 Due Date : 8/29/02	
5. Name of Drug Celebrex™ Capsules	6. Nonproprietary Name Celecoxib	
7. Supplement Provides for: Manufacture of a 400 mg capsule strength		8. Amendment(s) Faxes submitted to HFD 180 on 6/10/02 and 8/14/02
9. Pharmacological Category To treat acute and chronic pain associated with OA and RA	10. How Dispensed Rx	11. Related Documents NDA 21156/ S 001 and S 002
12. Dosage Form Capsules	13. Potency(ies) 400 mg	
14. Chemical Name and Structure See USAN		
15. Comments This is a PA supplement. Searle wishes to manufacture a 400 mg strength capsule so that instead of administering the approved dose of two 200 mg capsules a single 400 mg capsule can be administered for FAP. NDA 21-156 was submitted to and approved by HFD 180 for the FAP indication. Since the 400 mg strength capsule will be used for FAP, it was decided that this change (submitted in S/001 and S/002 to NDA 21-156) would be reviewed by HFD 180. As a result of that review by HFD 180 four deficiencies were cited that needed to be addressed. These deficiencies have now been addressed satisfactorily in Review # 2 of supplements 001 and 002 for NDA 21-156.		
16. Conclusions and Recommendations Recommend approval based on the recommendation made by HFD 180.		
17. Name Vispi P. Bhavnagri, Ph.D., Review Chemist	Signature	
Concurrence John Smith, Ph.D., Chemistry Team Leader		

APPROVAL

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/s/

Vispi Bhavnagri
8/28/02 12:57:23 PM
CHEMIST

John Smith
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