CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 20-830/S008

CHEMISTRY REVIEW(S)

Hilfiker

JAN 13 2000

CHEMIST'S REVIEW	1. ORGANIZATION HFD-570 DPDP	2. NDA NUMBER 20-830
3. NAME AND ADDRESS OF APPLICANT *(City and State)* Merck & Co., Inc. P.O. Box 4, BLA-20 West Point PA 19486		4. AF NUMBER 5. SUPPLEMENT(S) NUMBER(S) DATES(S) SEI-008 5/6/99 original *SEI-008 BC 12/2/99, 12/9/99 12/23/99 * subject of this review
6. NAME OF DRUG: Singulair® Chewable Tablets	7. NONPROPRIETARY NAME Montelukast sodium	
8. SUPPLEMENT PROVIDES FOR: 4 mg chewable tablets for pediatric use (2-5 years old)		9. AMENDMENT(S), REPORT(S), ETC. NUMBER(S) DATE(S)
10. PHARMACOLOGICAL CATEGORY Bronchodilator	11. HOW DISPENSED RX X OTC _	12. RELATED IND/NDA/DMF 20-829/SCS-007 4/8/99 20-830/SCS-007 4/8/99
13. DOSAGE FORM(S) Chewable tablets	14. POTENCY 4 mg/ml	
15. CHEMICAL NAME AND STRUCTURE Montelukast sodium		16. RECORDS AND REPORTS CURRENT YES__NO_ REVIEWED YES__NO_

17. COMMENTS:

a. The original efficacy supplement SEI-008 was submitted on 5/6/99.
b. This submission is in response to the Agency's IR letter dated 11/10/99.
c. Copies of the updated specification sheets (drug substance and the drug product) for 4 mg chewable tablets NDA 20-830 are attached to this review. See attachment-I.
c. A new EER for all manufacturing/testing sites was initiated. Except one location (commercial manufacturing, packaging and testing site at Wilson, NC with CFN No. 1036761), others sites were found acceptable by OC on 10/8/99.

18. CONCLUSIONS AND RECOMMENDATIONS:

a. From CMC viewpoint, this supplement is approvable pending receipt of satisfactory EER result for Wilson Site, NC.
b. Labeling comment listed in draft deficiencies letter to this review should be forwarded to the applicant by the CSO.

cc:
Orig. NDA 20-830/SEI-008
HFD-570/div. File
HFD-570/HKhorshidi
HFD-570/GPoochikian
HFD-570/CSO/DHilfiker

R/D Init. by: Poochikian 1/13/2000
F/T by: HKhorshidi /S/
doc #

19. REVIEWER NAME: Hossein S. Khorshidi	SIGNATURE /S/	DATE COMPLETED 1/10/2000

Hilfiker

OCT 22 1999

CHEMIST'S REVIEW	1. ORGANIZATION HFD-570 DPDP	2. NDA NUMBER 20-830
3. NAME AND ADDRESS OF APPLICANT *(City and State)* Merck & Co., Inc. P.O. Box 4, BLA-20 West Point PA 19486		4. AF NUMBER 5. SUPPLEMENT(S) NUMBER(S) DATES(S) *SEI-008 5/6/1999 * subject of this review
6. NAME OF DRUG: Singulair® Chewable Tablets	7. NONPROPRIETARY NAME Montelukast sodium	
8. SUPPLEMENT PROVIDES FOR: 4 mg chewable tablets for pediatric use (2-5 years old)		9. AMENDMENT(S), REPORT(S), ETC. NUMBER(S) DATE(S) *SEI-008/BC 9/29/99
10. PHARMACOLOGICAL CATEGORY Bronchodilator	11. HOW DISPENSED RX X OTC _	12. RELATED IND/NDA/DMF 20-829/SCS-007 4/8/99 20-830/SCS-007 4/8/99
13. DOSAGE FORM(S) Chewable tablets	14. POTENCY 4 mg/ml	
15. CHEMICAL NAME AND STRUCTURE Montelukast sodium		16. RECORDS AND REPORTS CURRENT YES__NO_ REVIEWED YES__NO_

17. COMMENTS:

a. The original NDA 20-830 (5 mg chewable tablets) was approved on 2/20/98.

b. Copies of the latest and approved specification sheets (drug substance and the drug product) for 5 mg chewable tablets NDA 20-830 are attached to this review. See attachment-I.

c. Updated EER was initiated for all manufacturing sites. Except two sites (which the results are pending as of 10/12/99), the rest were found acceptable by OC on 10/8/99.

18. CONCLUSIONS AND RECOMMENDATIONS:

From CMC viewpoint, this supplement is approvable. However, before approval of the supplement, adequate response should be submitted to the comments listed in draft deficiencies list

cc:
Orig. NDA 20-830/SEI-008
HFD-570/div. File
HFD-570/HKhorshidi
HFD-570/GPoochikian
HFD-570/CSO/DHilfiker

APPEARS THIS WAY
ON ORIGINAL

R/D Init. by:__Poochikian 10/22/99
F/T by: HKhorshidi
doc #

19. REVIEWER NAME: Hossein S. Khorshidi	SIGNATURE /S/	DATE COMPLETED 10/20/99