CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 20-505/S-002
20-844/S-010

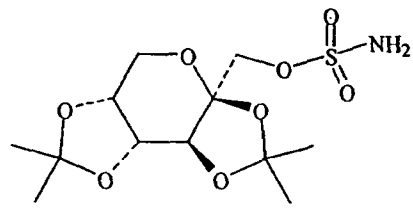
CHEMISTRY REVIEW

CHEMIST REVIEW OF SUPPLEMENT

1. **ORGANIZATION:** **HFD-120**
2. NDA NUMBER: **20-844**
4. SUPPLEMENT NUMBERS/DATES: SEI-010
   letterdate: 7-JUN-01
   stampdate: 8-JUN-01
5. AMMENDMENTS/REPORTS/DATES:
6. RECEIVED BY CHEMIST: 21-JUN-01

7. APPLICANT NAME AND ADDRESS: The R.W. Johnson Pharmaceutical Research Institute
920 Route 202 South
P.O. Box 300
Raritan, New Jersey 08869-0602

8. NAME OF DRUG: TOPAMAX® Sprinkle Capsules
9. NONPROPRIETARY NAME: topiramate
10. CHEMICAL NAME/STRUCTURE: 2,3:4,5-di-O-isopropylidene-β-D-fructopyranose sulfamate
[97240-79-4]



11. DOSAGE FORM(S): capsules
12. POTENCY: 15 mg, 25 mg, and 50 mg
13. PHARMACOLOGICAL CATAGORY: Adjunctive therapy in the treatment of seizures
14. HOW DISPENSED: XXX (RX) ___ (OTC)
15. RECORDS & REPORTS CURRENT: XXX (YES) ___ (NO)
SPECIAL PRODUCTS ___ (YES) XXX (NO)

16. RELATED IND/NDA/DMF: NDA 20-505 (Topamax Tablets) SEI-002

17. SUPPLEMENT PROVIDES FOR: A new indication (see above).

18. COMMENTS: The sponsor cross-refers to NDA 20-505 SEI-002, which is currently under review (Approvable Letter dated April 13, 2001). The sponsor provides draft labeling for this supplement to add the geriatric indication (S-006). No CMC changes are made in the labeling.

19. CONCLUSIONS AND RECOMENDATIONS: No CMC review is needed.

20. REVIEWER NAME	SIGNATURE	DATE COMPLETED
Mona Zarifa, Ph.D.	_____	22-JUN-01

cc: Orig. NDA 20-844
HFD-120/DivFile
HFD-120/JWare
HFD-120/MZarifa
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HFD-120/MGuzewska
INT: MG

filename: N20844S10.doc

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/s/

Mona Zarifa
6/27/01 04:46:11 PM
CHEMIST

Maryla Guzewska
6/28/01 07:53:25 AM
CHEMIST

NOV 5 1997

CHEMIST'S REVIEW OF SUPPLEMENT

ORGANIZATION: HFD-120
NDA NUMBER: 20-505
SUPPLEMENT NUMBERS: S-001/S-002/ S-003

LETTER DATE: 31-JUL-97
STAMP DATE: 01-AUG-97

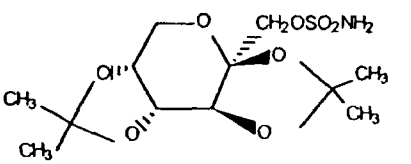
AMENDMENTS:

LETTER DATE: 29-OCT-97
STAMP DATE: 30-OCT-97

APPLICANT NAME & ADDRESS: **R.W. JOHNSON PHARMACEUTICAL RESEARCH INSTITUTE**
Welsh & McKean Roads
Spring House, PA 19477

NAME OF DRUG:
TOPAMAX™
NONPROPRIETARY NAME:

CHEMICAL NAME / STRUCTURE:



2,3:4,5-Bis-O-(1-methylethylidene)-β-D-fructopyranose sulfamate

DOSAGE FORM(S): Tablets
POTENCY(IES): 25, 50, 100, 200, and 300, 400-mg
PHARMACOLOGICAL CATEGORY: Epilepsy
HOW DISPENSED: XX (Rx) ___ (OTC)
RECORDS / REPORTS CURRENT: XX (YES) ___ (NO)
RELATED IND / NDA / DMF(S):
SUPPLEMENTS PROVIDE FOR: additional indications: pediatric, partial onset seizures, and Lennox-Gastaut Syndrome.
COMMENTS: In the October 29, 1997 amendment the firm withdraws their environmental assessment submission and files an application for categorical exclusion under the 21 CFR 314.60 new revised requirements (effective August 28, 1997). The firm provides statements to certify that the estimated concentration of topiramate at the point of entry into the aquatic environment remains at a level below 1 ppb.

CONCLUSIONS AND RECOMMENDATIONS: NDA 20-505 / S-001/S-002/S-003 include the adequate documentation for categorical exclusion from filing an environmental assessment.

REVIEWER NAME	SIGNATURE	DATE COMPLETED
Mona R. Zarifa, Ph.D.	/S/	November 4, 1997

cc: Orig.; NDA
HFD-120/Div. File
HFD-120/JWare
HFD-120/MGuzewska/MZarifa

Filename: 20505001.000

INIT: MG/ 11.5.97