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:
   letterdate:
   stampdate:
5. AMMENDMENTS/REPORTS/DATES:
6. RECEIVED BY CHEMIST:
   7-JUN-01
   8-JUN-01
   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 CATEGORICAL:
14. HOW DISPENSED:
    XXX (RX) — (OTC)
15. RECORDS & REPORTS CURRENT:
    XXX (YES) — (NO)
   — (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 RECOMMENDATIONS: No CMC review is needed.
20. REVIEWER NAME
    Mona Zarifa, Ph.D.
    ____________________________

SIGNATURE
DATE COMPLETED
22-JUN-01

cc: Orp. NDA 20-844
HFD-120/Div/Re
HFD-120/JWare
HFD-120/MZarifa
HFD-120/IZarifa
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
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
Mona R. Zarifa, Ph.D.

SIGNATURE

DATE COMPLETED
November 4, 1997

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

INIT: MG/48 w. 5.97

Filename: 20505001.000