

CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

20-637/S-016

Chemistry Review(s)

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| CHEMIST'S REVIEW #1 | | 1. ORGANIZATION HFD-150 DODP | | 2. NDA NUMBER 20-637 | |
| 3. NAME AND ADDRESS OF APPLICANT (City and State) Guilford Pharmaceuticals Inc. 6611 Tributary Street Baltimore, MD 21224 | | | | 4. AF NUMBER | |
| 6. NAME OF DRUG Gliadel [®] Wafer | | | | 7. NONPROPRIETARY NAME polifeprosan 20 with carmustine implant | |
| 8. SUPPLEMENT PROVIDES FOR: an expanded indication to include patients with malignant glioma undergoing primary surgical resection. It is an efficacy supplement. | | | | 9. AMENDMENTS DATES BC 6-1-2001 | |
| 10. PHARMACOLOGICAL CATEGORY Antineoplastic | | 11. HOW DISPENSED RX <input checked="" type="checkbox"/> OTC | | 12. RELATED IND/NDA/DMF | |
| 13. DOSAGE FORM(S) Wafer | | 14. POTENCY 3.85% BCNU 7.7mg BCNU/wafer | | | |
| 15. CHEMICAL NAME AND STRUCTURE 1,3-Bis(2-chloroethyl)-1-nitrosourea C ₅ H ₉ Cl ₂ N ₃ O ₂ , MW 214.05 | | | | 16. RECORDS AND REPORTS CURRENT YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> REVIEWED YES <input checked="" type="checkbox"/> NO <input type="checkbox"/> | |
| 17. COMMENTS This is an efficacy supplement for an expanded indication to include patients with malignant glioma undergoing primary surgical resection. This drug was approved by the Agency on September 23, 1996. The CMC regarding both drug substance and drug product remain unchanged. The container/carton labels also remain unchanged. The applicant claimed categorical exclusion according to 21 CFR 25.31(b). This supplement is recommended for approval from the CMC perspective. | | | | | |
| 18. CONCLUSIONS AND RECOMMENDATIONS Approval is recommended from the CMC perspective. | | | | | |
| 19. REVIEWER | | | | | |
| NAME Xiao Hong Chen, Ph.D. | | SIGNATURE  | | DATE COMPLETED 7-5-2001 | |
| <u>DISTRIBUTION</u> | ORIGINAL NDA | DIVISION FILE | Reviewer: Xiao Hong Chen HFD-150 | CSO: P. Zimmerman HFD-150 | Chemistry Team Leader: E. Duffy HFD-150 |

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/s/

Xiao Hong Chen
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CHEMIST

Eric Duffy
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CHEMIST