

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER: 20-450/S-004

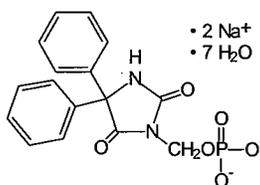
CHEMISTRY REVIEW

**CHEMIST'S REVIEW
OF ANNUAL REPORT**

ORGANIZATION: HFD-120
NDA NUMBER: 20-450
REPORT NUMBER: Y-004
LETTER DATE 04-OCT-2000
STAMP DATE 05-OCT-2000
RECEIVED BY CHEMIST: 24-OCT-2000

APPLICANT NAME AND ADDRESS: PARKE DAVIS, Div. of Warner-Lambert Co.
2800 Plymouth Road, P.O. Box 1047
Ann Arbor, MI 48106-1047

NAME OF DRUG: CEREBYX®
NONPROPRIETARY NAME: fosphenytoin sodium
CHEMICAL NAME / STRUCTURE: 5,5-Diphenyl-3-[(phosphonoxy)methyl]-2,4-imidazolidinedione disodium salt



DOSAGE FORM(S): Injection
POTENCY(IES): 75 mg/mL (equivalent to 50 mg/mL phenytoin sodium)
PHARMACOLOGICAL CATEGORY: Anticonvulsant
HOW DISPENSED: XX (Rx) (OTC)
RECORDS / REPORTS CURRENT: XX (YES) (NO)
RELATED IND / NDA / DMF(S): N/A

COMMENTS:

Changes reported in Y-004 are relatively minor, e.g. changing specifications to conform to compendial requirements or clarification of instructions. Changes reported are consistent with current CMC reporting requirements. [Refer to review notes.]

CONCLUSIONS AND RECOMMENDATIONS:

No action indicated.

Martha R. Heimann, Ph.D., Review Chemist

cc: Orig. NDA 20-450
HFD-120/JWare
HFD-120/MGuzewska/
HFD-120/MHeimann
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Review Completed: 18-APR-2001

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/s/

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