# CENTER FOR DRUG EVALUATION AND RESEARCH

# APPLICATION NUMBER: 20-450/S-005

# APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug
Administration
Rockville MD 20857

NDA 20-450/S-004
/S-005

Warner Lambert Company
c/o Pfizer, Inc.
Attention: Andrea Garrity
150 East 42nd Street
New York, NY 10017

Dear Ms. Garrity:

Please refer to the following supplemental new drug applications submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cerebyx® (fosphenytoin) Injection.

S-004
dated: March 1, 1999
amended: April 9, 1999

This supplemental application provides for revision of carton/container labeling to reflect concentration as a function of total container content rather than content per mL. This change was effected in response to several reports of overdose where health care providers mistakenly assumed that the amount of Cerebyx® per mL was the final amount provided by the total vial.

S-005
dated: June 24, 1999

This "Changes Being Effected" supplemental new drug application provides for revisions to the OVERDOSAGE section of the package insert to include specific adverse events that have been reported during cases of overdosage with Cerebyx®.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (carton/container submitted March 1, 1999; package insert submitted June 25, 1999). Accordingly, these supplemental applications are approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Jackie Ware, PharmD., Regulatory Management Officer, at (301) 594-2850.

Sincerely,

*{See appended electronic signature page}*

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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/s/

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Russell Katz
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