DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20450/S-036

SUPPLEMENT APPROVAL

Parke-Davis, a Division of Pfizer, Inc.
445 Eastern Point Road
Groton, CT 06340

Attention: Larry Cheng, MS
Manager, Essential Health Global Regulatory Affairs Brand

Dear Mr. Cheng:

Please refer to your Supplemental New Drug Application (sNDA) dated March 8, 2017, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Cerebyx (fosphenytoin sodium) injection.

This "Changes Being Effected" Supplemental New Drug Application provides for revised carton labels to include the statement, "For single-dose only. After opening, any unused product should be discarded."

APPROVAL & LABELING

We have completed our review of this supplemental application. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon carton labeling text.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, contact Cathy Michaloski, Sr. Regulatory Project Manager, by email at Cathleen.michaloski@fda.hhs.gov or by phone (301) 796-1123.

Sincerely,
{See appended electronic signature page}

Eric P. Bastings, M.D.
Deputy Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCL: Carton and Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ERIC P BASTINGS
03/10/2017