DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020450/S-024

SUPPLEMENT APPROVAL

Parke Davis, a Division of Pfizer Inc.
Attention: Denise Tindle
Director, Worldwide Safety and Regulatory
445 Eastern Point Rd.
Groton, CT 06340

Dear Ms. Tindle:

Please refer to your Supplemental New Drug Application (sNDA) dated and received September 10, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Cerebyx (fosphenytoin).

This "Changes Being Effected" supplemental new drug application provides for changes to container and carton labels which incorporate revisions requested by the Agency.

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

CARTON AND IMMEDIATE CONTAINER LABELS

We acknowledge your September 10, 2013, submission of containing final printed carton and container labels.

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 Laurie Kelley, PA-C, Regulatory Project Manager, via telephone at (301) 796-5068 or via email at Laurie.Kelley@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE(S):
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
10/22/2013