DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20450/S-029

SUPPLEMENT APPROVAL

Parke Davis, a Division of Pfizer, Inc.
235 East 42nd Street
New York, NY 10017

Attention: Denise S. Tindle, M.S.
Director, Worldwide Safety and Regulatory

Dear Ms. Tindle:

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

This supplemental application, submitted and received on September 11, 2015, as a "Changes Being Effected" supplement, proposes the following changes (underlined text added):

1. Addition to Dosage and Administration and How Supplied of the following statement:
   "For single-use only. After opening, any unused product should be discarded."

2. Addition to Dosage and Administration: IM or IV Substitution For Oral Phenytoin Therapy:
   When treatment with oral phenytoin is not possible, CEREBYX can be substituted for oral phenytoin at the same total daily phenytoin sodium equivalents (PE) dose. Dilantin capsules are approximately 90% bioavailable by the oral route…

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 labeling text.

CONTENT OF LABELING

As soon as possible, but no later 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, using the FDA automated drug registration listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling with the addition of any labeling changes pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(1)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean MS Word version. The marked-up copy should provide appropriate annotations, including supplemental number(s) and annual report date(s).

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, at (301) 796-1123, or by email at Cathleen.michaloski@fda.hhs.gov.

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 and Evaluation Research

ENCLOSURE:
Content of Labeling (Prescribing Information)

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
03/03/2016