DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20450/S-037; S-038
NDA 8762/S-060; S-061
NDA 10151/S-047; S-048

SUPPLEMENT APPROVAL

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

Attention: Larry Cheng
Manager, Pfizer Essential Health, GRA Brands

Dear Mr. Cheng:

Please refer to your Supplemental New Drug Applications (sNDAs), and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

Application	Product	Submitted on:	Received on:
NDA 08762/S-060	Dilantin-125 Oral Suspension, 125 mg phenytoin/5 mL	May 23, 2017	May 23, 2017
NDA 10151/S-047	Dilantin Injection, 50 mg phenytoin sodium/mL	May 23, 2017	May 23, 2017
NDA 08762/S-061	Dilantin-125 Oral Suspension, 125 mg phenytoin/5 mL	July 21, 2017	July 21, 2017
NDA 10151/S-048	Dilantin Injection, 50 mg phenytoin sodium/mL	July 21, 2017	July 21, 2017
NDA 20450/S-037	Cerebyx (fosphenytoin sodium) Injection	May 23, 2017	May 23, 2017
NDA 20450/S-038	Cerebyx (fosphenytoin sodium) Injection	July 21, 2017	July 21, 2017

These Prior Approval supplemental new drug applications (submitted July 21, 2017) and these "Changes Being Effected" supplemental new drug applications (submitted May 23, 2017) provide for changes to the prescribing information in Section 5 (Teratogenicity and Other Harm

to the Newborn subsection) and Section 8.1 (Use in Specific Populations; Pregnancy), and in Section 7.2 (Drug Interactions; Drugs Affected by Phenytoin [table of drugs whose level is decreased by phenytoin]—addition of disopyramide), respectively.

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. They are 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 than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and 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 (text for the package insert, Medication Guide), with the addition of any labeling changes in 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/DrugsGuidanceComplianceRegulatoryInformation/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(l)(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 Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement 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/call Cathy Michaloski, Sr. Regulatory Project Manager, at cathleen.michaloski@fda.hhs.gov or (301) 796-1123.

Sincerely,

{See appended electronic signature page}

Alice Hughes, M.D.
Deputy Director for Safety
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURES:
Content of Labeling

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

/s/

ALICE HUGHES
10/31/2017