



NDA 08762/S-057/S-058  
NDA 10151/S-044/S-045

## SUPPLEMENT APPROVAL

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

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

Dear Ms. Tindle:

Please refer to your Supplemental New Drug Applications (sNDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Dilantin (phenytoin) Injection (NDA 10151) and Oral Suspension (NDA 08762).

These supplemental applications, submitted and received on June 1, 2016 (Changes Being Effected) and June 2, 2016, (Prior Approval) propose the following changes:

**For Dilantin Injection label (10151/S-44) only** (underlined text):

### **DOSAGE AND ADMINISTRATION**

For single-use only. After opening, any unused product should be discarded.

### **HOW SUPPLIED**

For single-use only. After opening, any unused product should be discarded.

**For both Dilantin Injection label (10151/S-045) and Oral Suspension label (8762/S-57/S-058):**

Labeling consistent with the Physician Labeling Rule (PLR), including the Pregnancy and Lactation Labeling Rule (PLLR).

### **APPROVAL & LABELING**

We have completed our review of these supplemental applications, as amended. The applications 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(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).

### **PROMOTIONAL MATERIALS**

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above, by fax to 301-847-8444, or electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft Guidance for Industry (available at:

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM443702.pdf> ).

### **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](mailto: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

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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ERIC P BASTINGS  
11/30/2016