DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 008762/S-032/S-039/S-040/S-41

SUPPLEMENT APPROVAL

Pfizer Inc
Attention: Carol Haley
Director, Worldwide Regulatory Strategy
235 East 42nd Street
New York, NY 10017-5755

Dear Ms. Haley:

Please refer to your Supplemental New Drug Application (sNDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Dilantin-125® (phenytoin) Oral Suspension.

Application	Submitted on:	Received on:
NDA 008762/S-032	November 25, 2003	November 26, 2003
NDA 008762/S-039	August 28, 2009	August 28, 2009
NDA 008762/S-040	January 18, 2011	January 18, 2011
NDA 008762/S-041	January 18, 2011	January 18, 2011
NDA 008762/S-043	June 30, 2011	June 30, 2011

These "Changes Being Effected" supplements provide for:

- Package insert update of safety information including:
  1) Contraindications section- addition of hypersensitivity to inactive ingredients
  2) Drug Interactions section -edit to include additional information.
  3) Adverse Reactions section- edit to include additional information
- Package insert revision to include additional information in the Warnings and Precautions sections regarding serious skin reactions, hypersensitivity, and Anticonvulsant Hypersensitivity Syndrome.
- Package insert addition of fluorouracil to the Precautions/Drug Interactions section.
- Revise package insert language about osteomalacia in the Precautions section.
- Revision of Medication Guide

We acknowledge receipt of your amendment dated November 8, 2011.

We have completed our review of these supplemental applications, and our review of labeling revisions for NDA 008726, as amended, as follows: updating information regarding CYP450-mediated metabolism, adding a Contraindication to coadministration with delavirdine, additional revisions to the Drug Interactions section, to the Warnings section, and to the Adverse Reactions section. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

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, and 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 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).

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

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 or by fax to 301-847-8444.

OTHER

We request that you perform a comprehensive literature search and a comprehensive safety database search (of cases after June 30, 2001) to determine whether the Drug Interactions and Adverse Reactions sections of labeling should be further updated. Please submit an analysis of your findings and proposed related labeling changes as a Prior Approval Supplement within 3 months of the date of this letter.

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, call Su-Lin Sun, PharmD, Regulatory Project Manager, at (301) 796-0036.

Sincerely,

{See appended electronic signature page}

Russell G. Katz, M.D.
Division Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURE:
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/

RUSSELL G KATZ
12/14/2011