DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 08-762/S-036

Pfizer, Inc.
Attention: Robert Clark
Vice President, US Regulatory Affairs
235 East 42nd Street
New York, NY 10017-5755

Dear Mr. Clark:

Please refer to your supplemental new drug application dated January 14, 2009 and received January 14, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Dilantin-125® (phenytoin oral suspension, USP) Suspension.

Reference is also made to our letter dated December 16, 2008 notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for antiepileptic drugs, including Dilantin-125. This information pertains to the risk of suicidal thoughts or behaviors. Although not a part of the safety labeling changes, we also requested that you add language pertaining to the North American Antiepileptic Drug (NAAED) Pregnancy Registry, if it was not already present. No other labeling change requests submitted to date are addressed in this letter.

Our December 16, 2008, letter also notified you that, based on new safety information regarding the risk of suicidal thoughts or behaviors with AEDs, a Risk Evaluation and Mitigation Strategy (REMS) (including a Medication Guide) is required for Dilantin-125. In a March 17, 2009, letter we informed you that we had determined that the Medication Guide should be comprehensive and should include all risk information reflective of your labeling that is necessary for patients' safe and effective use of Dilantin-125. Any portion of your supplement that provides for a proposed comprehensive Medication Guide and proposed REMS has been administratively separated and will be acted on at a later date.

This supplemental new drug application includes revisions to the labeling for Dilantin-125 consistent with our December 16, 2008 letter.

We have completed our review of the safety labeling changes supplemental application, as amended. The safety labeling changes application 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 than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at

http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 08-762/S-036."

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and 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

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Tamy Kim, PharmD, Regulatory Project Manager, at (301) 796-1125.

Sincerely,

{See appended electronic signature page}

Russell Katz, MD
Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure: 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 Katz

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