DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 008762/S-042

SUPPLEMENT APPROVAL
RELEASE REMS REQUIREMENT

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

Dear Dr. Haley:

Please refer to your Supplemental New Drug Application (sNDA) dated April 26, 2011, received April 26, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Dilantin (phenytoin sodium) Oral Solution.

We acknowledge receipt of your risk evaluation and mitigation strategy (REMS) assessment dated April 26, 2011.

This supplemental new drug application proposes elimination of the requirement for the approved REMS.

We have completed our review of this supplemental application. It is approved, effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

The REMS for Dilantin (phenytoin sodium) was originally approved on January 17, 2011. The REMS consists of a Medication Guide and a timetable for submission of assessments of the REMS.

You proposed that FDA no longer require a REMS for Dilantin (phenytoin sodium).

We have determined that maintaining the Medication Guide as part of the approved labeling is adequate to address the serious and significant public health concern and meets the standard in 21 CFR 208.1. Therefore, it is no longer necessary to include the Medication Guide as an element of the approved REMS to ensure that the benefits of Dilantin (phenytoin sodium) outweigh its risks and a REMS is no longer required.

We remind you that the Medication Guide will continue to be part of the approved labeling in accordance with 21 CFR 208.

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, Senior Regulatory Project Manager, at (301) 796-0036.

Sincerely,

{See appended electronic signature page}

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

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
05/27/2011