DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 8-762/S-031

Pfizer Pharmaceuticals
Attention: Rita A. Wittich
Drug Regulatory Affairs
235 East 42nd Street
New York, NY 10017-3184

Dear Ms. Wittich:

We acknowledge receipt of your supplemental new drug application dated December 18, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Dilantin-125 (phenytoin oral suspension, USP) Suspension.

Reference is also made to an Agency letter dated November 20, 2001, requesting specific labeling revisions to the Dilantin labeling.

This "Changes Being Effected" supplement provides for revisions to remove the section, in the **PRECAUTIONS-General** section, regarding adverse events associated with the combination use of phenytoin, cranial radiation, and reduction of corticosteroids as requested in our November 20, 2001 letter. We additionally note that that you have added the statement "Not for Parenteral Use" to the prescriber labeling header and dosage information sections as well as to the container labeling for Dilantin-125 oral suspension.

We have completed the review of this supplemental application, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (labeling submitted December 18, 2002/Label Code 69-5938-00-2), which incorporates the revisions listed. Accordingly, this supplemental application is approved effective on the date of this letter.

Labeling changes of the kind which you have proposed under the above supplemental application are permitted by section 314.70(c) of the regulations to be instituted prior to approval of the supplement. It is understood that the changes, described in the above NDA supplement, have been made.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions regarding this letter, call Mr. Paul David, R.Ph., Senior Regulatory Project Manager, at (301) 594-5530.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug 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 Katz

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