DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug
Administration
Rockville MD 20857

NDA 10-596/S-017

Parke-Davis Pharmaceuticals Limited
c/o Pfizer Inc. (as Agent)
Attention: Denise Andrews
Director, Worldwide Regulatory Strategy
235 East 42nd Street
New York, NY 10017

Dear Ms. Andrews:

Please refer to your supplemental new drug application dated November 9, 2001, received November 9, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Celontin (methsuximide capsules, USP).

This "Changes Being Effected" supplemental new drug application provides for an update to the package insert for Celontin product to reflect the addition of the Pfizer name to the labeling.

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 draft labeling submitted November 9, 2001. Accordingly, this supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted November 9, 2001, immediate container and carton labels submitted November 9, 2001).

Please submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 10-596/S-017." Approval of this submission by FDA is not required before the labeling is used.

We also ask that you provide the actual bottle labels for the Celontin 150mg and 300mg strengths, either as an amendment to the current Annual Report, Y-033, or the next Annual Report.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" 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, call Jacqueline H. Ware, Pharm.D., Regulatory Project Manager, at (301) 594-5533.

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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