DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 10-596/S-009/S-012

Parke-Davis Pharmaceutical Research
Division of Warner-Lambert Company
Attention: Kenneth King
Drug Regulatory Affairs
2800 Plymouth Road
P.O. Box 1047
Ann Arbor, MI 48106-1047

Dear Mr. King:

Please refer to your supplemental new drug applications dated August 26, 1986 (S-009) and November 22, 1996 (S-012) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Celontin (methsuximide) 150 mg and 300 mg Capsules.

These supplemental applications provide for the following revisions to the Celontin labeling:

S-009
The addition of a list of inactive ingredients under the **DESCRIPTION** section of labeling.

We note that the **DESCRIPTION** section of labeling was revised with the changes provided for in S-016 which was approved in an Agency letter dated April 11, 2000. Therefore, the changes proposed in S-009 are now outdated.

S-012
The addition of a new subsection under **PRECAUTIONS** entitled **Pediatric Use** which references the practitioner to the **DOSAGE AND ADMINISTRATION** section.

We have completed the review of these supplemental applications 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 (package insert submitted November 22, 1996-Label Code 0537G091), which incorporates the revisions listed above. Accordingly, these supplemental applications are approved effective on the date of this letter.

We additionally request, at the next printing, the following revisions:

1. Please replace the presently used storage recommendations under the **HOW SUPPLIED** section of labeling as well as the container labels with the following statement:

   "Store at 25°C (77°F); excursions permitted to 15 - 30°C (59 - 86°F) [see USP Controlled Room Temperature]. Protect from light and moisture. Protect from excessive heat (104°F or 40°C)."

2. Please increase the prominence of the font for the generic name, methsuximide, on the container labels.

These changes as well as the changes approved under S-016 to the **DESCRIPTION** section of labeling should be reported in your next annual report.

Labeling changes of the kind which you have proposed under the above supplemental applications 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 supplements, 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, 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

/s/

Russell Katz
4/9/01 04:07:09 PM