DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-029/S005

Schering Corporation
2000 Galloping Hill Road
Kenilworth, NJ 07033

Attention: Joseph F Lamenola, Ph.D.
Vice President
Regulatory Affiars

Dear Dr. Lamendola:

Please refer to your supplemental new drug application dated September 12, 2002, received September 13, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Temodar® (temozolomide) Capsules 5, 20, 100, and 250 mg.

This supplemental new drug application proposes a change to the package insert for Temodar® by incorporating pediatric information on dosing, pharmacokinetics and safety.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text included in this letter.

Although this supplemental application is being approved, an indication for use in children will not be added to the label. There will not be any dosage information, pharmacokinetic data or efficacy data from the clinical studies in children added to the label. To do so would imply a pediatric use where efficacy for a pediatric use has not been demonstrated. The safety results from the clinical studies in children will be added to the Pediatric subsection of the PRECAUTIONS section of the label.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, text for the patient package insert.

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 21-029/S005." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Oncology Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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

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 Sean Bradley, R.Ph., Regulatory Project Manager, at (301) 301-594-5770.

Sincerely,

{See appended electronic signature page}

Richard Pazdur, M.D.
Director
Division of Oncology Drug Products
Office of Drug Evaluation 1
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Richard Pazdur

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