DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-029/S-008

Schering Corporation
2000 Galloping Hill Rd.
Kenilworth, NJ 07033

Attention: Mary Jane Boyle
Senior Director, Global Regulatory Affairs

Dear Ms. Boyle:

Please refer to your supplemental new drug application dated September 15, 2004, received September 15, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Temodar (temozolomide) Capsules 5, 20, 100, and 250 mg.

We acknowledge receipt of your submissions dated September 29, and November 10, 2004; and February 23; March 4, 9, and 15, 2005.

This supplemental new drug application provides clinical support for the use of Temodar Capsules for the treatment of patients with newly diagnosed high grade gliomas concomitantly with radiotherapy and then as adjuvant treatment.

We completed our review of this application, as amended. This application is approved for the use of Temodar Capsules for the treatment of patients with newly diagnosed glioblastoma multiforme concomitantly with radiotherapy and then as maintenance treatment, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the labeling submitted March 15, 2005.

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-029/S-008**." Approval of this submission by FDA is not required before the labeling is used.
We approved this NDA under the regulations at 21 CFR 314 Subpart H for accelerated approval of new drugs for serious or life-threatening illnesses. Approval of this supplement fulfills your commitments made under 21 CFR 314.510.

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 this division 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, HFD-410
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) 594-5770.

Sincerely,

{See appended electronic signature page}

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

Enclosures: Package Insert Labeling
Pharmacist Information Sheet
Patient Information Sheet

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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