DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-029/S-009

Schering Corporation
2000 Galloping Hill Road
Kenilworth, NJ 07033

Attention: Ketan Patel
Associate Manager, Global Regulatory Affairs

Dear Mr. Patel:

Please refer to your supplemental new drug application dated September 23, 2004, received September 24, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Temodar (temozolomide) Capsules 5, 20, 100, and 250mg.

We acknowledge receipt of your submission dated November 16, 2004.

This "Changes Being Effected" supplemental new drug application provides for an addition of the following text to the WARNINGS section of the package insert:

> Very rare cases of myelodysplastic syndrome and secondary malignancies, including myeloid leukemia have also been observed.

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.

As this labeling change qualified as a CBE, this statement was incorporated into the labeling of your recently approved efficacy supplement (S-008); approval date March 15, 2005. As stated in the approval letter for supplement 008, the final printed labeling (FPL) must be identical to the agreed upon labeling which was included in the approval letter.

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 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/

Richard Pazdur

3/30/05 03:00:20 PM