DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-029/S-008, S-011

Schering Corporation
2000 Galloping Hill Road
Kenilworth, NJ 07033

Attention: Susan Aygen
Associate Manager
Global Regulatory Affairs

Dear Ms. Aygen:

Please refer to your supplemental new drug application dated October 6, 2005, received October 7, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Temodar (temozolomide) Capsules.

We acknowledge receipt of your submissions dated May 24 and October 6, 2005.

We have reviewed the labeling for S-008 that you submitted in accordance with our March 15, 2005 letter and we find it acceptable.

This "Changes Being Effected" supplemental new drug application (S-011) provides for a change in the **ADVERSE REACTIONS IN ADULTS** section; **Refractory Anaplastic Astrcytoma** subsection of the product labeling and for a correction to the **Table 8. Dosing Modification Table.**

We have completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the text submitted on October 6, 2005.

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

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-011**." Approval of this submission by FDA is not required before the labeling is used.

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
Food and Drug Administration

WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Tammie Brent-Steele, Regulatory Project Manager, at (301) 796-1409.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D.
Acting Director
Division of Drug Oncology Products
Office of Oncology Drug Products
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/

Robert Justice

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