



NDA 21-029/S-007

Schering Corporation  
2000 Galloping Hill Road  
Kenilworth, NJ 07033

Attention: Mary Jane Boyle  
Global Regulatory Affairs

Dear Ms. Boyle:

Please refer to your supplemental new drug application dated December 22, 2003, received December 23, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Temodar (temozolomide) Capsules 5, 20, 100, and 250 mg.

This "Changes Being Effectuated" supplemental new drug application provides for updated safety changes to the ADVERSE EVENTS IN ADULTS section of the package insert.

We 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 draft labeling submitted on December 22, 2003.

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 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement(b)(4)----- 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, HFD-410  
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 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 1

Center for Drug Evaluation and Research

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/s/

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Richard Pazdur  
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