DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021029/S-018
NDA 022277/S-001

SUPPLEMENT APPROVAL

Schering-Plough Corporation
Attention: Barbara Gunther, MA, MBA
2000 Galloping Hill Road
Kenilworth, NJ 07033-0530

Dear Ms. Gunther:

Please refer to your supplemental new drug applications, sNDA 021029/S-018 dated March 31, 2009, received April 1, 2009, and sNDA 022277/S-001 dated March 31, 2009, received March 31, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Temodar (temozolomide), 100 mg Capsules and for Injection 100mg/vial.

We acknowledge receipt of your amendment dated April 8, 2010.

These Changes Being Effected supplemental new drug applications for sNDA 021029/S-018 and sNDA 022277/S-001 provide for revisions to the Adverse Reactions/Postmarketing Experience subsection to include "Cases of interstitial pneumonitis/pneumonitis, alveolitis, and pulmonary fibrosis have been reported".

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling text for the package insert. These revisions are terms of the sNDA approval. For administrative purposes, please designate these submissions, "SPL for approved NDA 021029/S-018 and NDA 022277/S-001".

REPORTING REQUIREMENTS

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 Amy Tilley, Regulatory Project Manager, at 301-796-3994.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D., M.S.
Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22277	SUPPL-1	SCHERING CORP	TEMODAR
NDA-21029	SUPPL-18	SCHERING CORP	TEMODAR (TEMOZOLOMIDE)

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

/s/

ROBERT L JUSTICE
04/26/2010