DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

TRANSMITTED BY FACSIMILE

Mary Jane Nehring
Senior Director, Marketed Products, Support, and Training
Worldwide Regulatory Affairs
Schering Corporation
2000 Galloping Hill Road
Kenilworth, NJ 07033

RE: NDA # 21-029
Temodar® (temozolomide) Capsules
MACMIS ID # 10141

Dear Ms. Nehring:

This letter notifies Schering Corporation (Schering) that the Division of Drug Marketing, Advertising, and Communications (DDMAC) has identified promotional activities that are in violation of the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations. Specifically, Schering gave false or misleading efficacy information about Temodar to visitors to the commercial exhibit hall booth at the 37th American Society of Clinical Oncology (ASCO) Annual Meeting (Meeting) held in San Francisco, California in May 2001. Schering also promoted Temodar for the unapproved use of first line therapy of anaplastic astrocytoma.

False or Misleading Efficacy Information

While presenting survival study results for Temodar at the commercial exhibit booth,[1] Schering's representative claimed that Temodar's survival results were compared to placebo. This claim is false or misleading because the approved product labeling (PI) states that the study in question was " a single arm multicenter study" and "No results are available from randomized controlled trials in recurrent anaplastic astrocytoma that demonstrate a clinical benefit resulting from treatment, such as improvement in disease-related symptoms, delayed disease progression, or improved survival."

Promotion of Unapproved Use

The Schering representative went on to claim that "we have tons of data on first-line use" and asked to scan the visitors name badge to send this information by mail. However, Temodar is indicated for "the treatment of adult patients with refractory anaplastic astrocytoma, i.e., patients at first relapse who have experienced disease progression on a drug regimen containing a nitrosourea and procarbazine." Thus, the representative's claim shows that

[1] Representative was referring to the presentation "Measurable Survival Results" in the Temodar promotional brochure, TE0005A/22419609.

Schering intended for Temodar to be used for the unapproved use of first-line therapy of anaplastic astrocytoma.

Requested Actions

Schering should immediately cease making such violative statements and any other promotional activities or materials for Temodar that make the same or similar claims or presentations. Schering should submit a written response to DDMAC on or before July 13, 2001, describing its intent and plans to comply with the above. In its letter to DDMAC, Schering should include the date on which this and other similarly violative materials were discontinued.

Schering should direct its response to me by facsimile at (301) 594-6771 or by written communication at the Division of Drug Marketing, Advertising, and Communications, HFD-42, Rm. 17B-20, 5600 Fishers Lane, Rockville, MD 20857. In all future correspondence regarding this matter, please refer to MACMIS ID # 10141 in addition to the NDA number. DDMAC reminds Schering that only written communications are considered official.

Sincerely,

{See appended electronic signature page}

Joseph A. Grillo, Pharm.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications

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

/s/

Joseph Grillo
6/28/01 11:44:26 AM