DEPARTMENT OF HEALTH & HUMAN SERVICES

M. Mancavage

Food and Drug Administration
Rockville MD 20857

**TRANSMITTED VIA FACSIMILE**

Ronald G. Van Valen
Drug Regulatory Affairs
Novartis Pharmaceuticals Corporation
59 Route 10
East Hanover, New Jersey 07936

MAR 11 1999

RE: **NDA 50-735**
Neoral® (cyclosporine capsules and oral solution for microemulsion)
MACMIS ID # 7678

Dear Mr. Van Valen:

As part of its routine monitoring program, the Division of Drug Marketing, Advertising and Communications (DDMAC) has become aware of promotional materials for Neoral® (cyclosporine capsules and oral solution for microemulsion) disseminated by Novartis Pharmaceutical Corporation (Novartis) that violate the Federal Food Drug and Cosmetic Act and its implementing regulations. Reference is made to the following promotional material submitted under cover of Form FDA 2253: ACR Reprint Carrier (NRA-8020). DDMAC has reviewed this material and has determined that it promotes Neoral® in a manner that is false or misleading because it lacks fair balance.

The cover of the above referenced reprint carrier is entitled "Clinical Implications and Applications for Severe Rheumatoid Arthritis (RA)." The inside pages of the piece are devoted to the presentation of the American College of Rheumatology (ACR) criteria for clinical improvement of RA and the presentation of efficacy data from referenced published articles. The presentation of efficacy data include two large multicolored bar graphs and bulleted explanations. The front cover and inside pages of the reprint cover contain no risk information. The back cover of the reprint carrier contains several efficacy claims that appear in large colored font or next to colored bullet points. The only risk information on the reprint carrier appears at the bottom of the back cover in small font. Promotional materials must present information relating to the side effects and contraindications with a prominence and readability reasonably comparable to the presentation of effectiveness of the drug. Therefore, because the risk information presented in the reprint carrier is incomplete and not prominently presented in a manner comparable to the claims regarding efficacy, this material is considered false or misleading because it lacks fair balance.

Please refer to DDMAC's letter to Novartis dated September 22, 1997, providing comments on a similar proposed reprint carrier. The proposed reprint carrier referred to in the letter listed risk information on both the inside page and back cover. In its letter, DDMAC commented that the presentation would be considered lacking in fair balance or otherwise misleading because the prominence afforded fair balance was insufficient.

Novartis should immediately cease distribution of this and other similar promotional materials for Neoral® that contain the same or similar claims without prominently presenting important risk information. Novartis should submit a written response to DDMAC on or before March 19, 1999, describing its intent and plans to comply with the above.

Novartis should direct its response to the undersigned by facsimile at (301) 827-2831, or by written communication at the Division of Drug Marketing, Advertising, and Communications, HFD-40; Room 17B-20; 5600 Fishers Lane; Rockville, MD 20857. DDMAC reminds Novartis that only written communications are considered official.

In all future correspondence regarding this matter, please refer to MACMIS # 7678 and NDA 50-735.

Sincerely,

/S/

John C. Markow R.Ph., J.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications