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Food and Drug Administration  
Rockville MD 20857

MAR - 1 1999

**TRANSMITTED VIA FACSIMILE**

Susan Witham  
Associate Director, Drug Regulatory Affairs  
Novartis Pharmaceuticals Corporation  
59 Route 10  
East Hanover, NJ 07963

**RE: NDA #20-148**  
Migranal (dihydroergotamine mesylate) Nasal Spray  
MACMIS # 7648

Dear Ms. Witham:

Reference is made to Novartis Pharmaceutical Corporation's (Novartis) January 19, 1999, Form FDA 2253 submission to the Division of Drug Marketing, Advertising and Communications (DDMAC) for Migranal (dihydroergotamine mesylate) Nasal Spray. The submission includes a journal advertisement featuring a testimonial by Terrell Davis (ID # MIG5004). DDMAC has reviewed this journal ad and finds it to be false or misleading and in violation of the Federal Food Drug and Cosmetic Act.

Specifically, the testimonial is false or misleading because it presents an atypical response to Migranal. Migranal has not been proven to be an abortive medication for migraine. While it is likely that Migranal treatment would allow the average migraine sufferer to return to limited leisure activities, it is not likely that the migraneur would be able to endure vigorous activity associated with playing in a football game and "lead his team to victory."

To address these objections, DDMAC recommends that Novartis do the following:

1. Immediately discontinue the use of this journal advertisement and other promotional materials with the same or similar messages.
2. Respond to this letter, in writing, by March 9, 1999. This response should include Novartis' intent to comply with the above, a list of all violative promotional practices or materials with the same or similar issues, and Novartis' methods for discontinuing their use.

Ms. Susan Witham  
Novartis  
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If Novartis has any questions or comments, please contact the undersigned by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, rm. 17B-20, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds you that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID # 7648 in addition to the NDA number.

Sincerely,

/S/

Lisa L. Stockbridge, Ph.D.  
Regulatory Review Officer  
Division of Drug Marketing,  
Advertising and Communications