DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

TRANSMITTED BY FACSIMILE

Lynn Mellor, Associate Director
James Rawls, Assistant Director
Drug Regulatory Affairs
Novartis Pharmaceuticals Corporation
59 Route 10
East Hanover, NJ 07936

RE: NDA # 20-313
NDA # 20-823
Miacalcin (calcitonin-salmon) Nasal Spray
Exelon (rivastigmine tartrate) capsules
MACMIS # 9897

Dear Ms Mellor and Dr. Rawls:

As part of its routine monitoring and surveillance program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has become aware of convention panels for Miacalcin and Exelon that appeared in the commercial exhibit hall of the American Pharmaceutical Association meeting in March, 2001. The convention panels promote Novartis Pharmaceuticals Corporation's drug products in violation of the Federal Food, Drug, and Cosmetic Act and its implementing regulations. Specifically, we have the following objections:

Lack of Fair Balance

The convention panels lack fair balance because they provide information relating to the effectiveness of Miacalcin and Exelon but fail to provide any information regarding side effects and contraindications (including warnings and precautions). For example, the Exelon panel provides the indication (i.e., "for mild to moderate Alzheimer's Disease"), but fails to include important risk information such as the recently revised bolded warning regarding severe vomiting and esophageal rupture. Similarly, the Miacalcin panel provides the indication without any important risk information.

Failure to Submit

Promotional materials must be submitted to DDMAC under cover of Form FDA 2253 at the time of initial use. Our records indicate, however, that you have not yet submitted the Exelon convention panel.

Conclusion and Recommendation

You should immediately stop using these violative panels and all other promotional materials with the same or similar presentations. You should respond to this letter on or before April 16, 2001. Your response should include your intent to comply with this request and a list of all similarly violative materials that will be discontinued as a result of this letter. It should be directed to either of us by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising, and Communications, HFD-42, 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 # 9897 in addition to the NDA numbers.

Sincerely,

{See appended electronic signature page}

Margaret M. Kober, R.Ph.
Lisa L. Stockbridge, Ph.D.
Regulatory Review Officers
Division of Drug Marketing,
Advertising, and Communications

/s/

Margaret Kober
4/2/01 10:15:36 AM

Lisa Stockbridge
4/2/01 10:19:52 AM


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