DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 14 1998

TRANSMITTED VIA FACSIMILE

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

RE: **NDA#** 20-762
Nasonex (mometasone furoate monohydrate) Nasal Spray, 50 mcg
MACMIS# 6959

Dear Ms. Nehring:

It has come to the attention of the Division of Drug Marketing, Advertising, and Communications (DDMAC) that Schering Corporation (Schering) has disseminated a one-page direct-to-consumer (DTC) magazine ad for Nasonex (mometasone furoate monohydrate) Nasal Spray (NX0291A/21909904 7/98) that lacks fair balance and is misleading and therefore violates the Federal Food, Drug, and Cosmetic Act and implementing regulations.

"Nasonex can prevent most seasonal nasal allergy symptoms before they even start."

The above claim promoting Nasonex for the prevention of nasal symptoms lacks fair balance. Misleading claims in one part of the ad are not corrected by a brief summary of the full prescribing information in another distinct part of the ad. Although the side effect profile is disclosed in the ad, the limitation of the prevention indication should also be disclosed in the ad (i.e., starting prophylactic treatment with Nasonex is recommended 2 to 4 weeks prior to the anticipated start of the pollen season). In addition, the ad should also communicate that patients should use Nasonex at regular intervals (once-daily) since its effectiveness depends on regular use.

Schering should cease its dissemination and use of promotional materials, including other ads, that contain this and similarly violative presentations. Schering should respond in writing no later than August 28, 1998, and should include a list of all similarly violative materials and a description of its method of discontinuing its use.

Schering's response should be directed to 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 17-B-20, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds Schering that only written communications are considered official.

In all future correspondence, regarding this particular matter, please refer to MACMIS ID# 6959 in addition to the NDA number.

Sincerely,

/S/

Joan Hankin, JD
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications