DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JAN 5 1999

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# 7406

Dear Ms. Nehring:

As part of its routine monitoring and surveillance program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed a press release issued from Schering Corporation (Schering) on December 11, 1998, through PRNewswire "Expert Panel Recommends Improved Detection and Treatment to Reduce Effects on Children's Health and Well-Being", regarding Nasonex (mometasone furoate monohydrate) Nasal Spray.

Nasonex is indicated for patients 12 years of age and older. However, Schering's press release promotes the safe and efficacious use of Nasonex for an unapproved pediatric population:

"Recent published studies examining the use of Nasonex in children between 3 and 12 years of age found no detectable systemic effects of the medication after 2 weeks of treatment. According to Dr. Scadding, this extremely low potential for systemic effects makes Nasonex an excellent choice for use in children with allergic rhinitis, particularly those who also take glucocorticoid medications for other ailments."

Based on the above statements, the December 11, 1998, press release is in violation of the Federal Food, Drug, and Cosmetic Act and its implementing regulations (see 21 CFR 312.7) because the labeling promotes an unapproved use for a prescription drug product by making undemonstrated claims of safety and efficacy.

DDMAC requests that the distribution and use of any materials containing these and similar unsubstantiated and misleading claims cease immediately, including but not limited to, the removal of this press release from the PRNewswire website.

Schering should respond in writing no later than January 20, 1999, 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# 7406 in addition to the NDA number.

Sincerely,

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