DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FOI

Food and Drug Administration
Rockville MD 20857

APR 27 1998

TRANSMITTED VIA FACSIMILE

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

RE: NDA# 19-658
Claritin (loratadine) Tablets
MACMIS# 6583

Dear Ms. Nehring:

As part of its routine monitoring activities, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed a product advertisement in a Sunday April 26, 1998, Giant Discount Drug newspaper circular (titled "Allergies Are Nothing To Sneeze At" *CR2299/21233900) for Claritin (loratadine) Tablets. DDMAC has determined that this* prescription drug product ad lacks fair balance as well as a brief summary and is, therefore, in violation of the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations.

Headline: "Allergies Are Nothing To Sneeze At"

> "One out of every five people suffers from allergies. The spring and fall seasons can be the worst for many allergy sufferers. If you suffer from allergies, ask your doctor or Giant Pharmacist about medications that can reduce or eliminate symptoms."

Because of these claims, this is a prescription drug product ad, rather than a reminder ad, that according to the Act and regulations, should include an accompanying brief summary of product risk information (i.e., relating to side effects and contraindications (including warnings and precautions) and the effectiveness of the drug). As a product ad, it should include a statement in the body of the ad signaling the reader to the brief summary (e.g., please see important product information below).

Furthermore, the ad lacks any fair balance disclosure (i.e., it fails to present information relating to side effects and contraindications, including warnings and precautions).

DDMAC requests that the distribution and use of this material and similar promotional materials cease immediately. Schering's written response should be received by DDMAC no later than May 11, 1998, and should include a list of all similarly violative materials and a description of its method of discontinuing their use.

Please direct your response 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 # 6583 in addition to the NDA number.

Sincerely,

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