DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

JUL 9 1997

Ronald J. Garutti, MD
Director, Marketed Products Support
Worldwide Regulatory Affairs
Schering Corporation
2000 Galloping Hill Road
Kenilworth, NJ 07033

RE: NDA# 19-658
Claritin (loratadine) Tablets
MACMIS# 5577

Dear Dr. Garutti:

As part of its routine monitoring activities, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed promotional materials for Claritin (loratadine) Tablets (e.g., AIDS CR1635A and CR1637A, brochure CR1632A) and has determined that these materials contain unsubstantiated superiority and/or misleading comparative claims, and are therefore violative of the Federal Food, Drug, and Cosmetic Act and its implementing regulations.

In such promotional materials, the superiority headline "Unlike cetirizine, Claritin gets the job done..." is misleading because it implies that cetirizine is not effective in the treatment of chronic idiopathic urticaria. However, Zyrtec (cetirizine) Tablets is indicated for the treatment of chronic idiopathic urticaria. In addition, under this superiority headline, the two bulleted comparative claims with graphs are not substantiated by substantial evidence (i.e., adequate and well-controlled studies) because they are cited to only one head-to-head study by Guerra et. al., ("loratadine and cetirizine in the treatment of chronic urticaria" J. Eur Acad Derm Vener. 1994;3:148-152).

DDMAC requests that the distribution and use of these materials and similar promotional materials cease immediately. Schering's written response should be received by DDMAC no later than July 23, 1997 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 # 5577 in addition to the NDA number.

Sincerely,

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