DEPARTMENT OF ... LTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

OCT - 8 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 19-658
Claritin (loratadine) Tablets
MACMIS ID# 8076

Dear Ms. Nehring:

This letter concerns a piece of homemade promotional labeling (i.e., a dear doctor letter) disseminated by a Schering Corporation/KEY Pharmaceuticals (Schering) sales representative, [ ] to a physician in his sales territory [ ] in April 1999. This homemade piece lacked fair balance, made unsubstantiated claims disparaging the safety of a competitive product, and made an unsupported superiority claim ("The medical community in the U.S. has clearly made *Claritin* their product of choice...."). The Division of Drug Marketing, Advertising, and Communications (DDMAC) has concluded that this promotional labeling violates the Federal Food, Drug, and Cosmetic Act and its implementing regulations.

Unsubstantiated Claim of Cardiotoxicity Based on a Case Study Report
Referring to a case study report from the journal *Lancet,* the dear doctor letter made unsubstantiated claims of cardiotoxicity about Allegra (fexofenadine HCl) Capsules:

"I wanted to bring to your attention a recent article that appeared in "The Lancet." The subject of cardiotoxic reactions with antihistamine use has again become a topic of discussion. This time the product in question is not *Seldane* but instead its active metabolite, *Allegra.*"

"I wrote this letter to you...,because I feel that the *Lancet* article clearly shows that there are concerns with cardiotoxicity with *Allegra* just like there were with its parent compound, *Seldane*..."

Ms. Mary Jane Nehrin
Schering Corporation
NDA# 19-658

On July 2, 1999, we sent Schering a written inquiry about the dissemination of this material and requested a response to our questions. We also requested copies of any written or verbal communications Schering provided to its sales force that referenced any claims of actual or potential cardiac safety problems with use of Allegra. On July 16, 1999, Schering responded to DDMAC stating that the dear doctor letter was not distributed to any healthcare professional other than the one identified individual. Schering also provided copies of corporate communications about its description of the company's internal use of the *Lancet* report.

While we acknowledge your statement that the dissemination of this violative material has ceased, we remind Schering that you are responsible for assuring that your sales force's promotional activities are in compliance with the Federal Food, Drug, and Cosmetic Act and its implementing regulations.

Any questions or comments should be directed to the undersigned by facsimile at (301) 594-6771 or by mail at the Food and Drug Administration, Division of Drug Marketing, Advertising, and Communications, HFD-40, Rm 17-B-20, 5600 Fishers Lane, Rockville, Maryland 20857. We remind Schering that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID# 8076 in addition to the NDA number.

Sincerely,

/S/

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