DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 19 1997

TRANSMITTED VIA FACSIMILE

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

RE: NDA# 19-658
Claritin (loratadine) Tablets
MACMIS ID# 5738

Dear Dr. Garutti:

This letter concerns Schering Corporation's (Schering) two broadcast product advertisements for Claritin (loratadine) Tablets. Based on Schering's representation that these are currently running advertisements, DDMAC has determined that these advertisements are violative of the Federal Food, Drug, and Cosmetic Act and its implementing regulations.

Specifically, both advertisements are misleading because the risk information disclosed as part of the required "major statement" is not presented in a manner comparable to that used to present the information relating to efficacy. The drug use information is presented clearly and slowly. In contrast, while the major statement information concerning the most common side effects is being presented in the audio part of the advertisement, there is a competing message being disclosed simultaneously. The video part of the advertisement presents a different risk-related disclosure concerning the dosage-related increase in drowsiness. These competing messages coming from different modalities virtually ensure that consumers will have trouble comprehending fully any of the messages. In addition, the major statement information is read so quickly that, even if the competing messages issue was addressed, it would still be difficult for the typical consumer to comprehend the major statement.

For the advertisement identified as PXCR-7933, DDMAC advises Schering that its mechanism for ensuring "adequate provision" for disseminating the approved package labeling for Claritin in connection with the broadcast advertisement is not adequate. FDA issued a draft guidance on August 8, 1997, that clarified the Agency's current thinking regarding one acceptable multi-faceted approach for fulfilling the requirements for the disclosure of product information in connection with consumer-directed broadcast advertisements for prescription human drugs such as Claritin. The TV advertisement in question lacks a mechanism to provide package

labeling to consumers with restricted access to sophisticated technology, such as the Internet, as well as those who are not active information seekers. There is no statement that additional product information can be obtained at various publicly accessible, convenient locations like groceries or libraries.

For the advertisement identified as PXCR-7923, DDMAC advises Schering that the disclosure relating to its mechanism to provide package labeling to consumers with restricted access to sophisticated technology, such as the Internet, as well as those who are not active information seekers is not adequate. Specifically, the disclosure that additional product information can be found in Newsweek magazine is obscured for at least half of the period of time the disclosure is on screen by its placement in white type against a white background.

In addition, in both advertisements, the disclosure relating to the component of the "adequate provision" procedure that should direct the viewer to their doctor or pharmacist for additional product information does not adequately accomplish this communication. The viewer is merely told to "ask your doctor or pharmacist." This vague phrasing undermines the purpose of this part of an "adequate provision" procedure, which is to let the consumer know that there is additional product information they can get from different sources.

Schering should immediately discontinue the use of the above television advertisement, and any other promotional materials that are misleading and/or lack adequate balancing risk information. Although DDMAC recognizes that Claritin has few serious side effects, we are concerned that television viewers have not received adequate balancing risk information for Claritin. DDMAC invites Schering to meet with us to discuss the above violative advertisements and ways to assure that such violations do not occur with future pieces.

Schering should respond to DDMAC in writing regarding this issue no later than August 26, 1997, and its response should include a description of its plan to address this issue, and its intent to meet with DDMAC to discuss the above issues. Schering's response should be directed to the undersigned 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 # 5738 in addition to the NDA number.

Sincerely,

Warren Rumble
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications