DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

SEP - 8 1997

TRANSMITTED VIA FACSIMILE

Alexander R, Giaquinto, Ph.D.
Senior Vice-President
Worldwide Regulatory Affairs
Schering Corporation
Galloping Hill Road
Kenilworth, NJ 07033

RE: NDA# 19-658
Claritin (loratadine) Tablets
MACMIS ID# 5760

Dear Dr. Giaquinto:

This letter concerns Schering Corporation's (Schering) broadcast product advertisement for Claritin (loratadine) Tablets. As part of the Division of Drug Marketing, Advertising, and Communications' (DDMAC) monitoring program, DDMAC has determined that the television advertisement aired the week of August 25, 1997, is violative of the Federal Food, Drug, and Cosmetic Act and its implementing regulations.

Specifically, the television advertisement refers viewers to "1-800-CLARITIN" for further risk information. However, when the viewer telephones the 1-800 number for risk information, consumers hear promotional messages, must respond to a marketing survey, and must provide their name and mailing address prior to hearing any information about the drug's side effects. If the consumer responds no to the statement, "nobody in your household suffers from seasonal allergy," the recording ends without providing risk information. If one listens to the full recording, the delay between contacting the telephone recording and hearing information about the major risks is approximately four minutes. Furthermore, detailed information (a reading of the approved product labeling) is provided only if the consumer calls a second 1-800 number that it not identified until approximately five minutes into the recorded message of the first 1-800 number.

Finally, when the prescribing information is provided, Schering does so by reading the entire approved product labeling from the beginning without branching and section selection. Consumers seeking information about adverse reactions or dosage and administration would have to wait an unacceptable length of time.

As described above, the response to consumers who call the 1-800-CLARITIN number fails to fulfill the "adequate provision" requirements[1].

On August 27, 1997, Norman Drezin and Warren Rumble of DDMAC contacted Joe Lamendola and Barbara Matlosz of Schering to relay DDMAC's concerns about the 1-800 telephone recording as described above. On August 29, 1997, and September 2, 1997, Schering submitted revised 1-800 number scripts. DDMAC has reviewed the September 2, 1997, revised 1-800 telephone script and has no objections to it at this time. Accordingly, we now consider the matter closed.

If you have any questions, please contact me or by telephone at (301) 827-2831, by facsimile at (301) 594-6771, or by written communication at the Division of Drug Marketing, Advertising, and Communications, HFD-40; Room 17B-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 # 5760 in addition to the NDA number.

Sincerely,

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

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[1]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.