DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 10 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# 5210

Dear Dr. Garutti:

This letter concerns a broadcast product ad in the form of a 1-800-CLARITIN recorded telephone script in use by Schering Corporation (Schering) for Claritin (loratadine) Tablets. DDMAC considers this broadcast product ad to be violative of the Federal Food, Drug, and Cosmetic Act and its implementing regulations because it does not provide adequate provision of the approved product labeling. DDMAC requests that further distribution and use of this ad, as well as any other similarly violative recorded telephone scripts for other Schering products, cease immediately.

The 1-800-CLARITIN telephone script recording represents a full product ad in the form of a broadcast ad. Under the regulations, a broadcast ad must include a "major statement" and adequate provision of the approved product labeling or presentation of a brief summary of all necessary information related to side effects and contraindications. According to the Claritin telephone recording, the Claritin product materials would be received by the caller "within the next few days." DDMAC does not consider a two-three week actual response time for receipt of the Claritin approved product labeling to meet the "adequate provision" requirement (as was the circumstance recently when this 1-800 number was called).

Schering's written response should include a description of its plan to address this issue. Schering's written response should be received by DDMAC no later than March 24, 1997, and 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 # 5210 in addition to the NDA number.

Sincerely,

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

File Name: claritin\adeqprov.nov

Drafted:	HANKIN	Date: 3/3/97
Comment:	O'BRIEN	Date: 3/5/97
Revised:	HANKIN	Date: 3/6/97
Concur:	DREZIN	Date: 3/6/97

CC:
HFD-40/NDA # 19-658
HFD-40/Chron/HANKIN(2)/ABRAMS/DREZIN

MACMIS ID # 5210

MACMIS Type Code: LETT
MACMIS Action Code: VIOL

Close Out: N

Due Date: March 24, 1997

FOI STATUS: RELEASABLE