DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

MAR 3 1997

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

RE: **NDA#** 20-641
Claritin (loratadine) Syrup 10mg/10mL
MACMIS ID# 5157

Dear Dr. Garutti:

This letter concerns a broadcast product television (tv) commercial (CS-0092 30-seconds) for Claritin (loratadine) Syrup 10mg/10mL that Schering Corporation (Schering) disseminated. The Division of Drug Marketing, Advertising, and Communications (DDMAC) has concluded that the commercial is in violation of the Federal Food, Drug, and Cosmetic Act and its implementing regulations because Schering disseminated a broadcast product ad without including information relating to the major side effects and contraindications of the product, and did not provide adequate dissemination of the approved product labeling or present a brief summary of all necessary information related to side effects and contraindications in connection with the broadcast commercial. DDMAC requests that further distribution and use of this commercial cease immediately.

On November 6, 1997, DDMAC provided launch comments to Schering on a proposed Claritin Syrup tv commercial, and stated we would object to various representations about the product in the commercial, including representations about use of Claritin Syrup in children and about the product's lack of interference on the activity level of children. Although Schering revised the commercial prior to its current dissemination, the tv commercial continues to contain representations related to the product. See below for examples of representations in the ad:

The combination of visual and audible elements that emphasize use of Claritin Syrup in children and suggest that use of the product will not interfere with a child's activity level and attention:

- "A/The prescription medicine for a family like yours", "...the medicine made for people with things to do ... And places to go..."

- in combination with graphics of the child roller blader as he: "weaves his way through a playground where children are playing, goes past a surreal classroom setting, bursts through the Claritin Syrup droplet past kids playing soccer, spins around and comes to a stop holding his thumb up"; and

- other images of kids playing baseball and a grandmother and child reading together.

The tv commercial should be discontinued immediately because it makes representations about the product and thus cannot qualify as a reminder ad, and the commerical has not fulfilled the regulatory requirements for a full product ad.

Schering's written response should be received by DDMAC no later than March 17, 1997, and should be directed 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 #5157 in addition to the NDA number.

Sincerely,

Joan Hankin

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

File Name: clarsyrp\remindtv.nov

Consult:	OSTROVE	Date: 2/26/97
Drafted:	HANKIN	Date: 2/27/97
Concur:	ABRAMS	Date: 2/27/97
Concur with Comment:	BAYLOR-HENRY	Date: 3/1/97
Revised:	HANKIN	Date: 3/3/97

CC:
HFD-40/NDA #20-641
HFD-40/Chron/HANKIN(2)/ABRAMS/OSTROVE/BAYLOR-HENRY

MACMIS ID # 5157

MACMIS Type Code: LETT
MACMIS Action Code: VIOL

2253ID#: 49635 Material ID#:CS0092

Due Date: March 17, 1997

Close Out: N

FOI STATUS: RELEASABLE