DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 26 1997

TRANSMITTED VIA FACSIMILE

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

RE: NDA# 20-470
Claritin-D 24 Hour
(10 mg loratadine and pseudoephedrine 240 mg sulfate) Extended-Release Tablets
MACMIS ID# 5238

Dear Dr. Garutti

This letter concerns a broadcast product television (tv) commercial ("Reveal Lift" CH0054, 15 seconds) for Claritin-D 24 Hour (10 mg loratadine and pseudoephedrine 240 mg sulfate) Extended-Release Tablets 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, rather than a reminder 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.

The following voice-over statement was made in the tv ad: "You've heard about Claritin, now ask your doctor about Claritin-D 24." This combined reference to Claritin in the Claritin-D 24 ad makes a representation or suggestion about the advertised product (e.g., representations regarding the availability of another safe and effective product (Claritin-D 24), or that another therapy (Claritin-D 24) is now available for use in treating some of the uses for which Claritin is indicated for). Such representations take the tv ad out of the realm of a reminder ad and make it broadcast product ad, for which this commercial has not fulfilled the above regulatory requirements. Therefore, DDMAC requests that further distribution and use of this tv commercial and other tv commercials containing similar claims cease immediately.

Schering's written response should be received by DDMAC no later than April 9, 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 #5238 in addition to the NDA number.

Sincerely,

Joan Hankin

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

File Name: clartd24\tvclartn.nov

Drafted: HANKIN Date: 3/20/97
Concur: ABRAMS Date: 3/25/97

CC:
HFD-40/NDA #20-470
HFD-40/Chron/HANKIN(2)/ABRAMS/OSTROVE

MACMIS ID #5238

MACMIS Type Code: LETT
MACMIS Action Code: VIOL

2253 ID#: 49571 Material ID#: CH0054 1/97 :15 seconds ("Reveal Lift")

Close Out: N

Due Date: April 9, 1997

FOI STATUS: RELEASABLE