



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

MAR 14 2000

Ms. Mary Jane Nehring  
Director, Worldwide Regulatory Affairs  
Schering Corporation  
2000 Galloping Hill Road  
Kenilworth, NJ 07033

**RE: NDA# 19-658**  
Claritin (loratadine) Tablets  
MACMIS ID#: 8778

Dear Ms. Nehring:

This letter addresses Schering Corporation's (Schering) dissemination of two television broadcast "reminder" advertisements for Claritin (loratadine) Tablets ("Spring" CR3430) and Claritin Syrup ("Goofing Around" CS0373). The Division of Drug Marketing, Advertising, and Communications (DDMAC) reviewed these advertisements as part of its monitoring and surveillance program and concluded that they are in violation of the Federal Food, Drug, and Cosmetic Act and applicable regulations.

Reminder advertisements call attention to the name of the drug product, but may not contain written, printed, or graphic matter containing representations or suggestions relating to the drug product. The overall presentation of the ads make a representation about the drug products, through the totality of the video images, especially the images of hay bales and loose hay flying around the actors' faces.

Schering should immediately cease using these television advertisements and all other promotional materials for Claritin that contain the same or similar claims or presentations. We should receive your written response no later than March 28, 2000, and it should list similarly violative materials, with a description of your method of discontinuation, and the discontinuation date.

Your response 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-42, Rm 17-B-20, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds Schering that only written communications are considered official.

Ms. Mary Jane Nehring  
Schering Corporation  
NDA#: 19-658

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In all future correspondence, regarding this matter, please refer to MACMIS ID# 8778 in addition to the NDA number.

Sincerely,

**/S/**

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

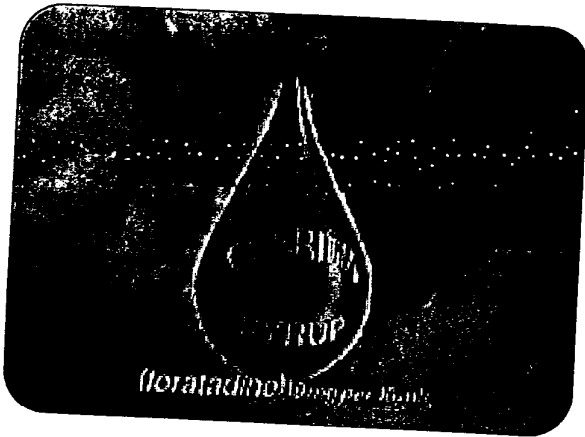
CLIENT: Schering

PRODUCT: Claritin® Base

TITLE: "Syrup - Goofing Around" 15-second with VO

ISCI CODE: PXC9 9471

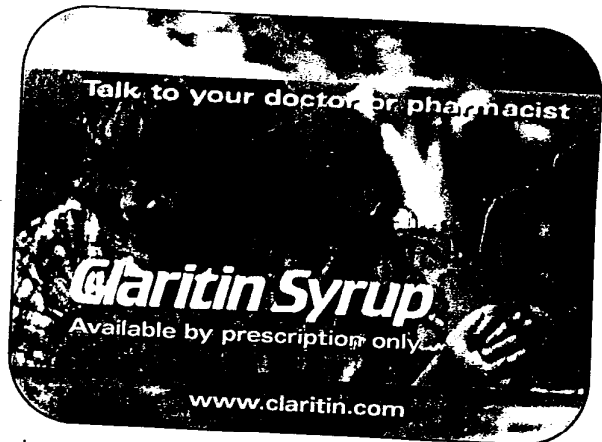
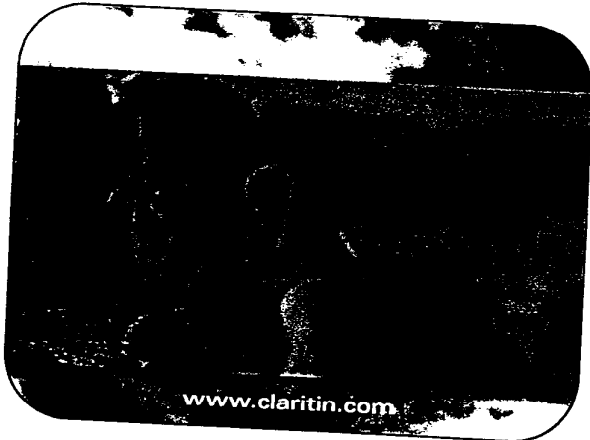
DATE: 02/09/2000



MUSIC: Walking on Sunshine



VO: Talk to your child's doctor



about CLARITIN® Syrup.

CS0373A/23720507 2/00

[ ]

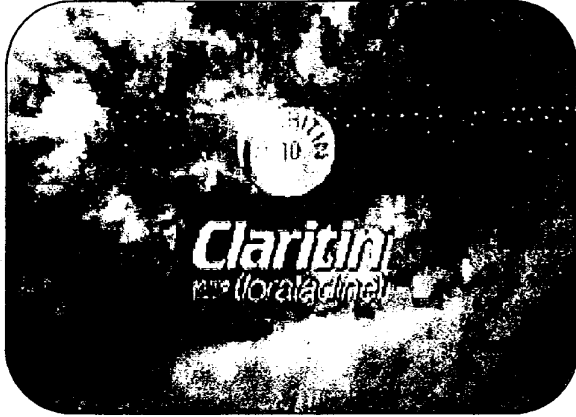
CLIENT: Schering

PRODUCT: Claritin® Base

TITLE: "Spring" 15 second with VO-Rev 1

ISCI CODE: PNCR 9511

DATE: 02/09/00



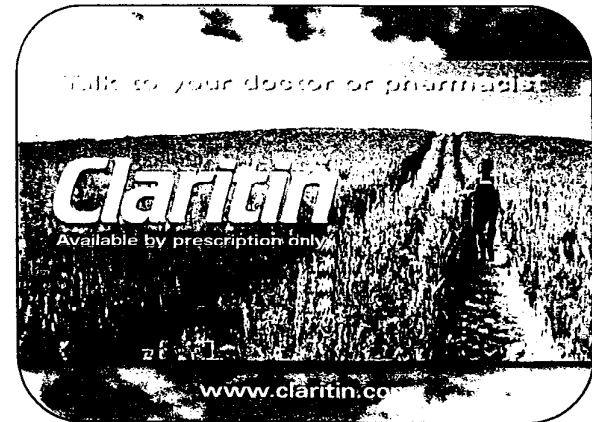
MUSIC: Walking on Sunshine



VO: It's another beautiful day.



Talk to your doctor



about CLARITIN®.