



MAY 26 2000

TRANSMITTED VIA FACSIMILE

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#: 9004

Dear Ms. Nehring:

This letter concerns Schering Corporation's (Schering) dissemination of a piece of health professional promotional labeling (i.e., sales aid CRM1062) for Claritin (loratadine) Tablets. The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed this sales aid and concluded that it contains a misleading safety claim. This promotional material violates the Federal Food, Drug, and Cosmetic Act and applicable regulations and should be discontinued immediately.

The sales aid includes the headline "Safe, Simple Options" with various claims, including "Approved by the FAA for use by pilots." The presentation of this safety claim implies that the Federal Aviation Administration (FAA) has unconditionally approved the use of Claritin for airline pilots.

However, this claim is misleading without additional context qualifying the FAA "approval." Furthermore, this unqualified promotional presentation could have safety implications. As you are aware, such a FAA medical certification is granted on an individual basis and only after a pilot meets certain conditions regarding use of the medication. These conditions include documenting that the pilot used the medication long enough to demonstrate stability and absence of unacceptable side effects that might affect aviation safety.

Schering should immediately cease using promotional materials for Claritin that contain the same or similar claims or presentations. We should receive your written response no later than June 12, 2000, and it should list similarly violative materials, with a description of your method of discontinuation, and the discontinuation date.

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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.

In all future correspondence, regarding this matter, please refer to MACMIS ID# 9004 in addition to the NDA number.

Sincerely,

A stylized handwritten signature in black ink, appearing to be the initials 'JH' or 'JD' with a flourish.

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

Safe, Simple Options

Claritin
10 mg
TABLETS (loratadine)

Claritin Syrup
(loratadine) 10 mg per 10 mL

Claritin RediTabs
10 mg (loratadine rapidly-disintegrating tablets)

- ✓ QD dosing: 24-hour relief
- ✓ For patients aged 6 years and older
- ✓ Indicated for both SAR and CIU
- ✓ May be taken without regard to meals
- ✓ An association between CLARITIN® and tachyphylaxis is unfounded
- ✓ Nonsedating*: no labeling precautions on patient activities (such as driving)
- ✓ Approved by the FAA for use by pilots
- ✓ Approved for use in military pilots†
- ✓ Outstanding safety profile
- ✓ Pregnancy category B

* The incidence of sedation with CLARITIN® (8%) was similar to that of placebo (6%) at the recommended dose. In studies with CLARITIN® at doses 2 to 4 times higher than the recommended dose of 10 mg, a dose-related increase in the incidence of somnolence was observed.

† After initial grounding period.