DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUN 14 2000

TRANSMITTED VIA FACSIMILE

Dan Henry, R.Ph., Pharm.D.
Assistant Director, US Regulatory Affairs, Marketed Products
Aventis Pharmaceuticals
10236 Marion Park Drive
P.O. Box 9627
Kansas City, MO 64134-0627

RE: NDA# 20-625
Allegra (fexofenadine hydrochloride) Capsules 60 mg
MACMIS ID# 9068

Dear Dr. Henry:

This letter concerns Aventis Pharmaceuticals' (Aventis) dissemination of a piece of professional promotional labeling (i.e., mock newspaper 50054813/20015803/0737C0) for various Allegra products, particularly Allegra Capsules 60 mg. The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed this piece and concludes that it contains a misleading safety claim. This promotional piece violates the Federal Food, Drug, and Cosmetic Act and applicable regulations and should be discontinued immediately.

The piece includes the bolded claim "Allegra is authorized by the FAA for pilots and air traffic controllers" (cited to Data on File, Aventis Pharmaceuticals). The presentation of this safety claim implies that the Federal Aviation Administration (FAA) has unconditionally approved the use of Allegra for airline pilots and air traffic controllers.

However, this claim is misleading without additional context qualifying the FAA "authorization." 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 or air traffic controller meets certain conditions regarding use of the medication. These conditions include documenting that the pilot or air traffic controller has used the medication long enough to demonstrate stability and absence of unacceptable side effects that might affect aviation safety.

Aventis should immediately cease using promotional materials for Allegra that contain the same or similar claims or presentations. We should receive your written response no later than June 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. We remind Aventis that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID# 9068 in addition to the NDA number.

Sincerely,

/S/

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

Allegra is authorized by the FAA for pilots and air traffic controllers[2]

- Authorized by the US Air Force for pilots with appropriate waiver[2]
- Authorized by the US Navy for naval aviators with appropriate waiver[2]
- Well suited for patients who need to stay alert