DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FOI

SEP 23 1998

TRANSMITTED VIA FACSIMILE

Mr. Dan Henry
Senior Regulatory Analyst
North American Regulatory Affairs
Hoechst Marion Roussel, Inc.
10236 Marion Park Drive
P.O. Box 9707
Kansas City, MO 64134-0707

RE: NDA# 20-625
Allegra (fexofenadine hydrochloride) Capsules 60 mg
MACMIS ID# 7054

Dear Mr. Henry:

As part of its monitoring and surveillance program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has become aware of journal advertisements disseminated by Hoechst Marion Roussel, Inc., (HMR) for Allegra (fexofenadine HCl) Capsules that are in violation of the Federal Food, Drug, and Cosmetic Act and applicable regulations. Specifically, DDMAC refers to the journal ad that appears in a recent issue of *Time* Magazine.

The ad states "Imagine - the only reaction caused by pollen is spring fever. This would definitely bring a sigh of relief to every person suffering from an allergy. To make this come true, the scientists at our pharmaceutical company, Hoechst Marion Roussel, are conducting extensive research. And today doctors are already able to prescribe effective antihistamines which reduce the allergic reaction without making the patient drowsy..." A close-up photograph of a man's smiling face looking outdoors beyond green vegetation, as well as the HMR name, logo, and website appear in this ad. These presentations suggest that HMR is marketing effective prescription antihistamines that do not cause drowsiness. DDMAC considers this to be a product-specific ad for Allegra and objects for the following reasons:

The ad is misleading because it fails to provide any risk information relating to side effects and contraindications (including warnings and precautions) to balance the safety and effectiveness claims. Furthermore, this product-specific ad does not include an accompanying brief summary of risk information required by the advertising regulations. Finally, it appears this product-specific ad was not submitted upon first dissemination as required by 21 CFR 314.81(b)(3)(i).

HMR should immediately cease its dissemination and use of all promotional materials for Allegra that contain the same or similar violations. HMR should respond in writing no later than October 7, 1998, and should include a list of similarly violative materials or ad placements and a description of its method of discontinuing its use. HMR's response should be directed to the undersigned 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 HMR that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID# 7054 in addition to the NDA number.

Sincerely,

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