DEPARTMEI : HEALTH & HUMAN SERVICES Pu alth Service

Food and Drug Administration
Rockville MD 20857

NOV 26 1997

TRANSMITTED VIA FACSIMILE

Ms. Michelle Wallace
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# 5971

Dear Ms. Wallace:

This letter concerns promotional materials for Allegra (fexofenadine HCL) 60 mg capsules disseminated by Hoechst Marion Roussel (HMR). The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed these materials and determined that they make a misleading comparative cost claim and therefore violate the Federal Food, Drug, and Cosmetic Act and its implementing regulations.

HMR has disseminated various promotional labeling materials to managed care organizations (e.g., Sharp Rees - Stealy Medical Group 97269201/2013N7) that feature a chart entitled "Comparison of price, dose and dose schedules" that compares Allegra to Claritin (loratadine) Tablets. This chart contains the following comparative information:

"Avg Rx Price[/Cost]: Allegra - $38.77, Claritin - $57.00, % Difference - 47.0%" (footnote cite: IMS National Prescription Audit Plus: quarter ending March 1997. Actual data may vary."

The comparative price/cost conclusion of a "47% difference" is misleading because the above price/cost comparison is based on an undefined time frame and therefore the conclusion of a 47% difference suggests a greater savings than what is supported by average wholesale price data. Such cost comparison should be based on a standardized unit of time (i.e., cost-per-day), to account for differences in physicians' antihistamine prescribing patterns for individual patients.

HMR should cease its dissemination and use of promotional materials that contain these and similar violative claims immediately. HMR should respond in writing no later than December 11, 1997 and should include a list of all similarly violative materials and a description of its method of discontinuing their use.

HMR's 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-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# 5971 in addition to the NDA number.

Sincerely,

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