DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

OCT - 6 1999

TRANSMITTED VIA FACSIMILE

Ms. Peggy J. Berry
Senior Manager, Regulatory Affairs
Dey Laboratories
2751 Napa Valley Corporate Drive
Napa, CA 94558

RE: NDA#: 19-430
EpiPen and EpiPen Jr. (0.3 mg and 0.15 mg epinephrine auto-injector)
MACMIS ID# 8330

Dear Ms. Berry:

This letter concerns promotional materials disseminated by Dey Laboratories (Dey) for EpiPen and EpiPen Jr. (0.3 mg and 0.15 mg Epinephrine auto-injector) (i.e., journal advertisement 09-732-000 and multi-page brochure 09-543-00, entitled "Speed Saves"). The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed these promotional materials and concluded that they lack any fair balance disclosure of risk information. Therefore, they violate the Federal Food, Drug, and Cosmetic Act and implementing regulations.

Dey should immediately cease its dissemination and use of all promotional materials for EpiPen and EpiPen Jr. that lack fair balance. We should receive your written response no later than October 21, 1999, and it should list all similarly violative materials, with a description of your method for discontinuation. 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-40, Rm 17-B-20, 5600 Fishers Lane, Rockville, MD 20857. We remind Dey that only written communications are considered official.

Sincerely,

/S/

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