DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

SEP 16 1997

David Gardner
Director, Regulatory Affairs
Andrx Pharmaceuticals, Inc.
4001 Southwest 47th Avenue
Ft. Lauderdale, FL 33314

RE: **ANDA#** 74-852
DiltiaXT (diltiazem HCl) Extended Release Capsules
MACMIS ID# 5793

Dear Mr. Gardner:

As part of its routine monitoring program, the Division of Drug Marketing, Advertising and Communications (DDMAC) has become aware of promotional materials for DiltiaXT (diltiazem HCl) extended release capsules by Andrx Pharmaceuticals, Inc. (Andrx) that violate the Federal Food, Drug and Cosmetic Act and its implementing regulations. Reference is made to a "coming soon" advertisement that was published in the August 25, 1997 issue of Chain Drug Review '97 Annual Report of Retail Pharmacy.

Coming soon advertisements may announce the name of the new product that will be available soon. However, coming soon advertisements may not make written, verbal, or graphic representations or suggestions concerning the safety, efficacy, or intended use of the product. As you are aware, the Food and Drug Administration has not approved DiltiaXT for marketing. DDMAC has reviewed this ad and has determined that its distribution constitutes pre-approval promotion of DiltiaXT. Claims of "once daily" and "once-a-day dosage" make representations about DiltiaXT, and are therefore violative.

Andrx should immediately cease distribution of this and other similar promotional materials for DiltiaXT that contain the same or similar claims or presentations. Andrx should submit a written response to DDMAC on or before September 30, 1997, describing its intent and plans to comply with the above. Your response should also include the extent to which this coming soon advertisement was distributed.

Andrx should direct its response 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 17B-20, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds Andrx that only written communications are considered official.

In all future correspondence regarding this particular matter please refer to MACMIS ID #5793 in addition to the ANDA number.

Sincerely,

Janet Norden, MSN, RN
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications