DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 30 1998

TRANSMITTED VIA FACSIMILE

Dolores M. Fortunes
Manager
Regulatory Affairs
Carnick Laboratories, Inc.
65 Horse Hill Road
Cedar Knolls, NJ 07927

RE: NDA# 85-272
Bontril (phendimetrazine tartrate, USP) Tablets
MACMIS ID# 6441

Dear Ms. Fortunes:

Through routine monitoring and surveillance, the Division of Drug Marketing, Advertising and Communications (DDMAC) has become aware of a brochure (ID # 20M), disseminated by Carnick Laboratories, Inc. (Carnick) for Bontril, that is in violation of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder. Specifically, the brochure is lacking in fair balance because there is no risk information in the presentation.

To address this objection, DDMAC recommends that Carnick immediately discontinue the use of this brochure and all other promotional materials for Bontril that contain the same or similar presentations.

Please respond to this letter, in writing, by April 13, 1998. This response should include a list of all violative promotional materials and your method for discontinuing their use.

If Carnick has any questions or comments, please contact 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.

In all future correspondence regarding this particular matter, please refer to MACMIS ID #6441 in addition to the NDA number.

Sincerely,

Lisa L. Stockbridge, Ph.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications