DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FOI

JAN 23 1997

TRANSMITTED VIA FACSIMILE

Richard W. Tkach, JD
Associate Director
Labeling and Advertising, US Regulatory Affairs
Schering Corporation
2000 Galloping Hill Road
Kenilworth, NJ 07033

RE: **NDA#** 18-687
Normodyne® (labetalol HCL) Tablets
MACMIS ID #5036

Dear Mr. Tkach:

Reference is made to Schering Corporation's (Schering) submission of brochure #NR-1002A submitted under cover of FDA Form 2253, on December 4, 1996, for Normodyne® (labetalol HCL) Tablets. The Division of Drug Marketing, Advertising and Communications (DDMAC) has concluded that this promotional piece is in violation of the Federal Food, Drug and Cosmetic Act (the Act) and regulations promulgated thereunder. Our specific objections to the brochure are discussed below and should apply to all applicable promotional materials for Normodyne®.

> "The Joint National Committee on High Blood Pressure (JNC V) identified labetalol HCL as appropriate initial monotherapy for hypersensitive patients."
>
> "...(JNC V) has identified labetalol HCL as appropriate initial monotherapy."

These claims are false and/or misleading. According to JNC V's recommendations, several drugs are considered suitable for initial therapy. This presentation misrepresents JNC V's recommendations by taking them out of context. Unless contraindicated, beta-blockers and diuretics are the preferred agents because they were shown to reduce morbidity and mortality in controlled clinical trials. Labetolol HCL remains one of *many* alternative choices for initial therapy listed by JNC V, which also includes calcium antagonists, angiotensin converting enzyme inhibitors, and alpha$_1$- receptor blockers.

Additionally, in the first claim, the word "hypersensitive" needs further clarification if used to describe a patient. JNC V does not refer to labetolol HCL therapy as treatment specifically for "hypersensitive" patients. The use of this word lacks context to describe appropriate

antihypertensive drug therapy and is therefore misleading.
Schering should immediately discontinue use of this and other promotional materials that are similarly violative. Please respond in writing by February 6, 1997, with your intent to comply with the above. Address your response to the undersigned 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 Schering that only written communications are considered official.

In all future correspondence regarding the issues raised in this letter, please refer to MACMIS ID # 5036 in addition to the NDA number.

Sincerely,

Victoria J. Babb, Pharm.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications

File Name: normodyne.nov1

Drafted: Babb	Date: January 13, 1997
Comment: Hankin	Date: January 13, 1997
Revised: Babb	Date: January 13, 1997
Comment: Abrams	Date: January 14, 1997
Revised:Babb	Date: January 16, 1997
Comment:Hankin	Date: January 16, 1997
Revised: Babb	Date: January 17, 1997
Concur w/Comment: Abrams	Date: January 21, 1997

CC:
HFD-240/NDA # 18-687
HFD-240/Count/Chron/Babb(2)/Abrams
HFD-110/McDonald/Gordon
HFD-110/NDA # 18-687

MACMIS ID # 5036

MACMIS Type Code:	LETT
MACMIS Action Code:	VIOL

2253 ID#: 47120 Material ID#(s): NR1002A

Due Date:	February 3, 1997
Close Out:	N

NOV Status: RELEASABLE