DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

SEP - 5 1997

Rudolph W. Lucek
Group Director, Drug Regulatory Affairs
Hoffmann-La Roche Inc.
340 Kingsland Street
Nutley, NJ 07110-1199

RE: **NDA#** 20-689
Posicor (mibefradil dihydrochloride) Tablets
MACMIS ID# 5746

Dear Mr. Lucek:

As part of its routine monitoring program, the Division of Drug Marketing, Advertising and Communications (DDMAC) has become aware of promotional materials for Posicor (mibefradil dihydrochloride) tablets by Hoffman-La Roche Inc. (Roche) that violate the Federal Food, Drug and Cosmetic Act (Act) and its regulations. Reference is made to the following specific materials submitted under cover of Form FDA 2253: journal ad (17-090-074-004-077), and promotional letter (16-004-074-026-077). DDMAC has reviewed these materials for Posicor and has determined that they promote Posicor in a manner which is considered false and/or misleading. Our specific objections to the promotional messages will be discussed, and our comments should be applied to these and any similar messages located in other promotional pieces.

Journal ad

, Roche refers to Posicor's safety profile as
This claim implies superiority over other cardiovascular drug products. In DDMAC's letter dated July 28, 1997, comments were made on revised proposed launch materials for Posicor. In that letter, Roche was informed that DDMAC would object to use of the word when describing Posicor's safety, since this claim is not based on substantial evidence. DDMAC continues to consider this an unsubstantiated superiority claim which is false and/or misleading.

Promotional letter

In this and other promotional letters, Roche claims that Posicor is
Reference is made to DDMAC's letter dated July 3, 1997, in which

proposed launch materials for Posicor were reviewed. In that letter, DDMAC objected to the representations of the importance attributed to as false and/or misleading, since Roche had not provided sufficient evidence of the clinical significance of this mechanism of action. In its response, dated July 10, 1997, Roche stated "no clinical significance has been attributed to this property" and the following disclaimer was included in the proposed launch promotional material:

Because this disclaimer does not appear in the promotional letter, DDMAC would consider it false and/or misleading.

Since both of these promotional claims were addressed in Posicor's launch campaign, DDMAC is particularly concerned that Roche is distributing promotional materials which are in violation of the Act and its regulations. Therefore, Roche should immediately cease distribution of these and other similar promotional materials for Posicor that contain the same or similar claims or presentations. Roche should submit a written response to DDMAC on or before September 19, 1997, describing its intent and plans to comply with the above.

Roche 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 Roche that only written communications are considered official.

In all future correspondence regarding this particular matter please refer to MACMIS ID #5746 in addition to the NDA number.

Sincerely,

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