DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 21 1997

TRANSMITTED VIA FACSIMILE

Margaret J. Jack
Project Director
Drug Regulatory Affairs
Hoffman-La Roche, Inc.
340 Kingsland Street
Nutley, New Jersey 07110-1199

Re: NDA 20-766
Xenical (orlistat capsules)
MACMIS ID # 5744

Dear Ms. Jack:

This letter is in reference to Hoffman-La Roche's "coming soon" advertisement for its investigational new drug, Xenical. This advertisement appears in the August, 1997, issue of the Journal of the American Dietetic Association. The Division of Drug Marketing, Advertising and Communications (DDMAC) has determined that this advertisement is in violation of the Federal Food, Drug, and Cosmetic Act and applicable regulations.

Specifically, Roche presents promotional claims of efficacy for its new drug (Xenical) for which it is under investigation. For example, the headline states, "Coming Soon: A unique weight loss drug that acts nonsystemically."

DDMAC refers Hoffman-La Roche to the April 1994 guidance letter to Industry, which discussed pre-approval promotion. The regulations promulgated pursuant to the Act, 21 CFR 312.7, state that an investigational new drug may not be promoted as being safe and effective for the uses under investigation. Therefore, DDMAC usually considers pre-approval promotion of drug products to be violative. However, DDMAC has traditionally recognized two methods in which sponsors may discuss products under FDA review, without making promotional claims of safety or efficacy that are prohibited by the Act.

The first method of permissible pre-approval promotion is "Institutional Promotion." Institutional advertisements state that a particular drug company is conducting research in a certain therapeutic area to develop new and important drugs. The

advertisement may not suggest any particular drug by name or otherwise suggest that a particular drug will soon be approved for use in the therapeutic area under consideration.

The second method of permissible pre-approval promotion is "Coming soon promotion." Coming soon advertisements announce the name of a new product that will be available soon, but do not make written, verbal, or graphic representations or suggestions concerning the safety, efficacy, or intended use of the product.

This advertisement is not considered an institutional ad or "coming soon" ad because it makes representations about the product including its specific use and mechanism of action.

Therefore, this advertisement and similar violative promotion of Xenical should be discontinued immediately. Hoffman-La Roche should respond to this letter by September 4, 1997, indicating its intent to comply with this recommendation. This response should include a list of all similarly violative materials and a description of the method for discontinuing their use.

If Hoffman-La Roche has any questions or comments, please contact the undersigned by facsimile at (301)594-6771, or in writing at DDMAC, HFD-40, Room 17B-20, 5600 Fishers Lane, Rockville MD 20857.

In all correspondence related to this matter, please refer to MACMIS ID # 5744, in addition to the NDA number.

Sincerely,

Anne M. Reb, NP
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications