DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JUN - 6 1997

TRANSMITTED VIA FACSIMILE

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

Re:
Xenical (orlistat capsules)
MACMIS ID# 5436

Dear Ms. Jack:

This letter is in reference to Hoffman-La Roche's May 15, 1997, promotional material ("Dear Doctor" letter) for Xenical. The "Dear Doctor" letter discusses the FDA's Advisory Committee's recommendation for the approval of Xenical. The Division of Drug Marketing, Advertising and Communications (DDMAC) has reviewed this material and has determined that it is in violation of the Federal Food, Drug, and Cosmetic Act and applicable regulations.

The "Dear Doctor" letter is violative because Hoffman-La Roche presents promotional claims of safety and efficacy about its investigational drug, Xenical. Thus, the "Dear Doctor" letter and similar pre-approval promotion of Xenical should be discontinued immediately. Hoffman-La Roche should respond by June 20, 1997, indicating its intent to comply with this recommendation.

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 #5436, in addition to the NDA number.

Sincerely,

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