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MAY 14 1998

TRANSMITTED VIA FACSIMILE

Daniel L. Zabrowski, Ph.D.
Vice President & Global Head
Drug Regulatory Affairs
Hoffmann-La Roche Inc.
340 Kingsland Street
Nutley, NJ 07110-1199

Re:

Xenical (orlistat tetrahydrolipstatin)
MACMIS ID # 6660

Dear Dr. Zabrowski:

As part of its routine monitoring program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has become aware of a press release for Xenical (orlistat), dated May 13, 1998, which appeared on the Hoffman-La Roche (Roche) Internet web site, that is in violation of the Federal Food, Drug and Cosmetic Act (Act) and the regulations promulgated thereunder.

The press release contains the following statements: "Xenical is the first of a new class of non-systemically acting anti-obesity drugs called lipase inhibitors which act in the gastrointestinal tract to block the absorption of fat by about 30 percent;" and, "Xenical - in comparison to other agents - does not achieve its effect through brain chemistry." These statements represent in a promotional context that Xenical, an investigational new drug, is effective for the purpose for which it is under investigation in violation of the Act and implementing regulations.

Roche should immediately discontinue the dissemination of this press release and any promotional materials prior to the approval of Xenical. Roche should submit a written response to DDMAC on or before May 22, 1998, confirming that Roche has discontinued the use of such material.

If 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.

Dr. Daniel L. Zabrowski
Hoffmann-La Roche Inc.
Xenical

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In all correspondence related to this matter, please refer to MACMIS ID #6660 in addition to the NDA number. DDMAC reminds Roche that only written communications are considered official.

Sincerely,

Jayne E. Peterson, R.Ph., J.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications