



TRANSMITTED VIA FACSIMILE

OCT - 6 1999

Ms. Lynn Devenezia-Tobias
Program Manager
Drug Regulatory Affairs
Hoffmann-La Roche Inc.
340 Kingsland Street
Nutley, NJ 07110-1199

Re: **NDA 20-766**
Xenical (orlistat) Capsules
MACMIS ID # 8351

Dear Ms. Devenezia-Tobias:

As part of its routine monitoring program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has become aware of promotional materials for Xenical (orlistat) Capsules that are in violation of the Federal Food, Drug, and Cosmetic Act (Act) and the regulations promulgated thereunder. Specifically, DDMAC objects to a direct-to-consumer 60-second television advertisement ("Facts"), submitted by Hoffmann-LaRoche Inc. (H-R) under cover of Form FDA 2253 on October 4, 1999. A description of our objections is provided below.

Lacking in Fair Balance

The television advertisement is lacking in fair balance because the advertisement fails to present information relating to side effects and contraindications with a prominence reasonably comparable with the presentation of information relating to effectiveness of the drug. The risk information is presented in the audio portion of the advertisement concomitant with a visual presentation of the adequate provision components along with distracting sound effects. This presentation interferes with the audience's ability to comprehend and process the audio presentation disclosing Xenical's most important risks. In contrast, the efficacy information is clearly presented without any intervening distractions. In addition, the audio communication of the risk information is inadequate because it is not presented with a prominence, speed, or audibility reasonably comparable with the presentation of the product's benefits.

Major Statement

The major statement is inadequate to communicate the most important risks. Specifically, the statement, "you may experience gas or oil with discharge" is misleading because it does not adequately convey to consumers Xenical's risks of gas with discharge and oily discharge.

Indication Statement

The advertisement is misleading because it does not adequately communicate Xenical's indication from its approved product labeling. The audio presentation of the statement, "If you're considerably overweight," combined with the "super" (visual only) presentation of the statement, "Xenical (orlistat) is recommended for adults who are at least 30 lbs. overweight depending on height" does not adequately convey the limitations to the population of patients for whom treatment with Xenical is indicated. Specifically, this important information is not presented in a sufficiently prominent manner to enable comprehension and processing.

H-R should immediately discontinue the use of the broadcast advertisement and other promotional materials that contain the same or similar representations for Xenical discussed above. H-R should submit a written response to DDMAC on or before October 20, 1999, confirming that H-R has discontinued the use of such materials.

If H-R has any questions or comments, please contact Chin Koerner, M.S., M.Ed. or 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 #8351 in addition to the NDA number. DDMAC reminds H-R that only written communications are considered official.

Sincerely,



Michael A. Misocky, R.Ph., J.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications