



TRANSMITTED BY FACSIMILE

Lynn DeVenezia-Tobias
Program Manager, Drug Regulatory Affairs
Hoffmann-La Roche, Inc.
340 Kingsland Street
Bldg. 1/2
Nutley, NJ 07110-199

**RE: NDA #20-766
Xenical (orlistat) capsules
MACMIS #9845**

Dear Ms. DeVenezia-Tobias:

As part of its routine monitoring and surveillance program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has become aware of a direct-to-consumer television broadcast advertisement for Xenical entitled "Baby On A Scale, Body Mass Index," disseminated by Hoffmann La Roche, Inc. This advertisement promotes Xenical in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and its implementing regulations. Specifically, we object for the following reasons:

Reference to the Xenicare support program renders this broadcast advertisement a product-specific advertisement. Xenical is the only weight loss product with a support program named Xenicare.

Therefore, the advertisement is in violation of the Act and its implementing regulations because it identifies the specific product but does not contain information regarding Xenical's full indication or adequate provision for dissemination of the approved product labeling. Furthermore, the advertisement lacks fair balance.

In order to address these objections, we recommend that you take the following actions:

1. Immediately discontinue the use of this and all other similarly violative promotional materials.
2. Provide us with a statement, in writing, of your intent to comply with the above request. Your response should be received by April 13, 2001.
3. Include a list of all violative promotional materials and the method of their discontinuation with your response.

DeVenezia-Tobias
Hoffmann-La Roche
NDA 20-766

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If you have any questions or comments, please contact me by facsimile at (301) 594-6771 or at the Food and Drug Administration, Division of Drug Marketing, Advertising, and Communications, HFD-42, Rm. 17B-20, 5600 Fishers Lane, Rockville, MD 20857.

DDMAC reminds you that only written communications are considered official. In all future correspondence regarding this particular matter, please refer to MACMIS ID #9845 in addition to the NDA number.

Sincerely,

{See appended electronic signature page}

Margaret M. Kober, R.Ph.
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications

/s/

Margaret Kober

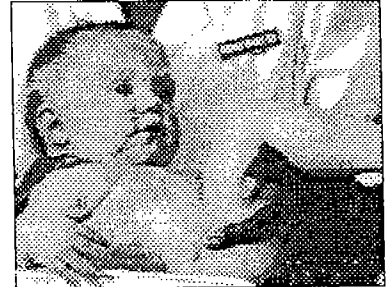
3/30/01 12:40:07 PM



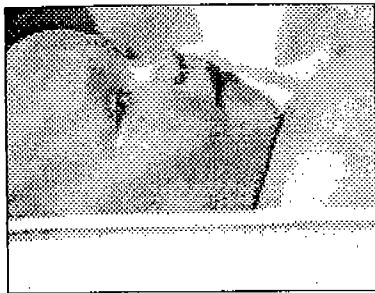
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FEMALE ANNCR: When you were a baby, you were put on a scale,



someone measured your height. So from the beginning, two important health statistics were already known about you:



your weight and your height. Ironically, today, those two measurements are just as important as the day you were born.



They determine your body mass index or BMI,



which can determine whether your weight may be putting your health at risk. To help you have a conversation about BMI with your doctor,



call this number and get a free conversation guide, plus information on our free, personalized (GRFX: 1 800 552-6424/CALL FOR FREE INFORMATION)



support program, Xenicare. (GRFX: HOW TO HAVE A HEALTHY CONVERSATION ABOUT WEIGHT WITH YOUR DOCTOR.)



Call, because your doctor now has truly different prescription options to help you



lose weight. Doctors have been weighing you since you were born. Isn't it time you talked with your doctor about getting back to a healthy weight. SUPER: WWW.WEIGHTLOSS.COM



Call now for your free conversation guide. (MUSIC OUT)