



**TRANSMITTED BY FACSIMILE**

Mr. Murad Husain  
Program Director  
Drug Regulatory Affairs  
Hoffman-La Roche Inc.  
340 Kingsland Street  
Nutley, NJ 07110-1199

**RE: NDA # 20-896**  
**Xeloda® (capecitabine) Tablets**  
**MACMIS ID# 10521**

Dear Mr. Husain:

This letter notifies Hoffman-La Roche Inc. (Roche) that the Division of Drug Marketing, Advertising, and Communications (DDMAC) has identified direct-to-consumer (DTC) print<sup>1</sup> and telephone broadcast<sup>2</sup> advertisements (ads) for Xeloda that are in violation of the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations. Our specific objections follow:

**Print Advertisement**

The print ad states "Finally, *oral chemotherapy* for metastatic colorectal cancer." (Italics in original print ad) This claim renders the print ad to be product-specific for Xeloda because Xeloda is the only oral chemotherapy agent approved for metastatic colorectal cancer. Therefore, the print ad is in violation of the Act because it identifies the specific product but does not contain information regarding Xeloda's full indication or a brief summary of information relating to contraindications, warnings, precautions, and side effects of Xeloda. Furthermore, the print ad lacks fair balance.

In addition, the print ad claims "It's less... distressing..." and "You'll gain freedom..." as compared to traditional chemotherapy. These claims for Xeloda are misleading because they are not supported by substantial evidence.

<sup>1</sup> "Imagine being here instead of the clinic" published in the November 12, 2001, issue of *TIME Magazine*.

<sup>2</sup> Telephone conversation with Roche at 1-888-229-3763, the toll-free number appearing in the above print ad.

### **Telephone Broadcast Advertisement**

The telephone broadcast ad is in violation of the Act because it identifies Xeloda as a treatment for colorectal cancer but fails to include the required statement of Xeloda's major side effects and contraindications (the "major statement"). Furthermore, the telephone broadcast ad lacks adequate provision for dissemination of the approved product labeling (PI).

In addition, promotional labeling materials for Xeloda (identified as PLANDEX 111135 and PLANDEX 111030) were sent by Roche in response to the caller's request during the telephone broadcast ad. These promotional labeling materials are in violation of the Act because they were not disseminated together with the PI.

### **Failure to Comply with CFR 314.81(b)(3)(i)**

The print and telephone broadcast ads were not submitted on Form FDA 2253 at the time of initial dissemination, in violation of the post-marketing reporting requirements of the Act.

### **Requested Action**

Roche should immediately cease the distribution of these and other similar promotional materials for Xeloda that contain the same or similar claims or presentations. Roche should submit a written response to DDMAC on or before January 24, 2002, describing its intent and plans to comply with the above. In its letter to DDMAC, Roche should include the date on which these and other similarly violative materials were discontinued.

Roche should direct its response to me by facsimile at (301) 594-6771 or by written communication at the Division of Drug Marketing, Advertising, and Communications, HFD-42, Rm. 17B-20, 5600 Fishers Lane, Rockville, MD 20857. In all future correspondence regarding this matter, please refer to MACMIS ID # 10521 in addition to the NDA number. DDMAC reminds Roche that only written communications are considered official.

Sincerely,

*{See appended electronic signature page}*

Joseph A. Grillo, Pharm.D.  
Regulatory Review Officer  
Division of Drug Marketing,  
Advertising, and Communications

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**This is a representation of an electronic record that was signed electronically and  
this page is the manifestation of the electronic signature.**  
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/s/

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Nancy Ostrove  
1/9/02 11:48:07 AM  
Signed for Joseph Grillo

# Imagine

being *here* instead of at the clinic.



Finally, *oral chemotherapy* for metastatic colorectal cancer.

- It's less intrusive and distressing than traditional chemotherapy
- You'll gain freedom and flexibility when planning your day around chemotherapy
- You can take it anywhere life leads you

Ask your doctor if oral chemotherapy is right for you or call 1-888-229-3763.