



**TRANSMITTED BY FACSIMILE**

Ms. Cynthia Dillon  
Program Director  
Drug Regulatory Affairs  
Hoffman-La Roche Inc.  
340 Kingsland Street  
Nutley, NJ 07100-1199

**RE: NDA# 21-087**  
Tamiflu (oseltamivir phosphate) Capsules  
MACMIS ID#: 10762

Dear Ms. Dillon:

This letter objects to Hoffman-La Roche Inc.'s (Roche) dissemination of a violative direct-to-consumer (DTC) radio broadcast advertisement (ad) for Tamiflu Capsules. The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed this Tamiflu radio ad (60 second "Eric Bergoust" submitted on Form FDA 2253) as part of its monitoring and surveillance program. DDMAC has concluded that Roche's radio ad is misleading, in violation of the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations for the following reasons.

**Omission of Material Facts Regarding Approved Indication and Use**

The radio ad is misleading because it omits material facts regarding the influenza treatment indication and use of Tamiflu. As stated in the approved product labeling (PI) "Tamiflu is indicated for the treatment of uncomplicated acute illness due to influenza (flu) infection in patients one year or older who have been **symptomatic for no more than two days**" (emphasis added). If a patient is not specifically informed that that he/she must take Tamiflu in the early stages of illness, and consequently takes it later in the illness, there is no evidence the drug will confer any benefit. The claim in the radio ad "So when I felt the flu symptoms again, I took Tamiflu" suggests that one could take Tamiflu several days after onset, and thus fails to convey, and indeed undermines, this critical efficacy-related prescribing information. It is therefore misleading.

### **Overstatement of Efficacy**

Promotional materials are misleading if they suggest that a prescription drug is more effective than has been demonstrated by substantial evidence (21 C.F.R. 202.1(e)(6)(i)). The claims in the Tamiflu radio ad featuring Olympic aerial skier Gold medalist, Eric Bergoust, misleadingly overstate the drug's efficacy. The totality of testimonial claims, such as "I felt better so soon that I didn't miss a single day of training" and "with the first dose things started to look up," markedly overstate the efficacy of Tamiflu treatment. The PI states that for flu patients taking Tamiflu compared to those on placebo, there was a 1.3 day reduction in the median time to flu symptom improvement. Therefore, this "felt better so soon" claim, along with other efficacy claims in the ad, misleadingly suggest Tamiflu works far more rapidly than has been demonstrated in clinical trials and that flu symptoms are eliminated by Tamiflu rather than merely alleviated.

Moreover, any statement of effect in any individual, and especially celebrity spokespersons such as Gold medalist Eric Bergoust (e.g., "Tamiflu worked great for me"), without further qualification about the representativeness of the claimed drug results (e.g., individual results may vary), represents an overstatement of drug efficacy. Collectively, the various testimonial statements and lack of context to qualify these claims is misleading.

### **Failure to Make Adequate Provision for Dissemination of the Approved or Permitted Package Labeling**

FDA's prescription drug advertising regulations (21 CFR 202.1(e)(1)) provide in pertinent part:

Advertisements broadcast through media such as radio, television, or telephone communications systems shall include information relating to the major side effects and contraindications of the advertised drugs in the audio or audio and visual parts of the presentation and *unless adequate provision is made for dissemination of the approved or permitted package labeling in connection with the broadcast presentation* shall contain a brief summary of all necessary information related to side effects and contraindications.  
(Emphasis added.)

The Tamiflu radio ad does not contain a brief summary. Consequently, the regulations require that adequate provision be made for dissemination of the approved package labeling in connection with the ad. The Tamiflu radio ad includes a toll-free telephone number and a website address to access the package labeling. These methods alone, however, do not constitute "adequate provision for dissemination" of the required information.

The "adequate provision" requirement necessitates an approach to dissemination that will allow most of a potentially diverse audience of consumers with different levels of mobility, different levels of access to technology, different sensitivity to privacy, and different information-seeking

styles to have reasonably convenient access to the Tamiflu approved package labeling. This broad audience will include, among others, persons who are uncomfortable directly requesting additional prescription drug product information from their healthcare providers, persons without access to computers and the Internet, persons who are uncomfortable actively requesting additional product information about a specific prescription drug, and persons concerned about providing phone numbers or other personal information in connection with their request. The methods provided in the Tamiflu radio ad do not address these significant populations and thus do not make "adequate provision for dissemination" of the important risk information.

FDA's Guidance for Industry on Consumer-Directed Broadcast Advertisements contains suggested mechanisms for reaching passive and privacy-sensitive information seekers, and those without access to technology. The Guidance suggests as possible mechanisms that brochures containing the required information be made available in a variety of public places such as libraries, pharmacies and grocery stores, or a reference in the broadcast ad be made to concurrent print ads containing a means to access the necessary risk information (e.g., toll-free telephone number and address) in publications reaching the exposed audience. These methods, of course, are not exclusive, and you may utilize other methods, as long as the totality of the mechanisms provided ensure that most of the audience exposed to the Tamiflu radio ad will have ready access to the required risk information.

#### **Requested Action**

Roche should immediately discontinue this and all other promotional materials and activities for Tamiflu that contain the same or similar presentations. We request that Roche respond in writing with its intent to discontinue such use. Please provide your written response no later than May 31, 2002. This response should list similarly violative materials with a description of the method for discontinuation and the discontinuation date.

Your response should be directed to the undersigned by facsimile at (301) 594-6771, or in writing at the Food and Drug Administration, Division of Drug Marketing, Advertising, and Communications HFD-42, Rm. 17-B-20, 5600 Fishers Lane, Rockville, Maryland 20857.

In all future correspondence on this matter, please refer to MACMIS ID# 10762 as well as the NDA number. DDMAC reminds you that only written communications are considered official.

Sincerely,

*{See appended electronic signature page}*

Joan Hankin, JD  
Consumer Promotion Analyst  
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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Joan Hankin

5/16/02 04:41:18 PM

3/1/02

ROCHE/TAMIFLU  
"Eric Bergoust Radio"  
Radio :60  
1/15/02

ERIC:

My name is Eric Bergoust

I'm so proud to have won the gold medal in aerial skiing in Nagano.

To win you have to overcome obstacles.

While training I even had to overcome the flu.

The first time I had the flu I was in bed for five days. Couldn't practice, couldn't move.

So when I felt the flu symptoms again, I took Tamiflu.

The team doctor wrote a prescription.

With the first dose things started to look up.

Tamiflu worked great for me.

Really helped stop the suffering.

I felt better so soon that I didn't miss a single day of training.

ANNCR VO:

"Tamiflu is an easy-to-take antiviral medication. 1 out of 10 may experience mild to moderate nausea or vomiting. Fewer may experience bronchitis, sleeplessness or dizziness. Tamiflu, also known as oseltamivir phosphate, is not a substitute for a flu shot."

ERIC:

My goal is to go to Salt Lake City and win another gold medal for the U.S. And nothing will get in my way, not even the flu.

ANNCR VO:

For information, call 1-800-IGOTFLU or visit [www.tamiflu.com](http://www.tamiflu.com).  
A message from Roche.