

**TRANSMITTED VIA FACSIMILE**

JUL 16 1999

Ms. Ellen R. Westrick  
Senior Director  
Office of Medical/Legal  
U.S. Human Health  
Merck & Co., Inc.  
P.O. Box 4, WP37C-116  
West Point, PA 19486

Re: **NDA 20-560 Fosamax (alendronate sodium)**  
**NDA 21-042 Vioxx (rofecoxib)**

**MACMIS ID # 8086**

Dear Ms. Westrick:

As part of its routine monitoring program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has become aware of promotional materials for Fosamax (alendronate sodium) and Vioxx (rofecoxib) that are lacking in fair balance or otherwise misleading. Reference is made to two direct-to-consumer (DTC) Broadcast Advertisements for Fosamax (MISC-FOS-8PR98), submitted under cover of Form FDA 2253 on June 9, 1999. Reference is also made to a DTC Print Ad for Vioxx, appearing in the July 7, 1999, issue of the *El Nuevo Dia*. The publication of these materials by Merck & Company, Inc. (Merck) violates the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations. DDMAC requests that the use of the above referenced material and those containing the same or similar violations cease immediately.

#### **Reminder Advertisements**

Reminder advertisements call attention to the name of the drug product, but may not contain written, printed, or graphic matter containing representations or suggestions relating to the advertised drug product.

Fosamax : Broadcast Ad-Script #3 "Women"

This advertisement in its entirety makes a representation or suggestion about Fosamax. The pictorial presentation of an active, menopausal or postmenopausal woman swimming coupled with the statements, "I don't feel I have changed and I certainly don't want my life to change" and "Discover Fosamax" makes a representation or suggestion about the use of Fosamax.

Vioxx : DTC Print Ad

This advertisement in its entirety makes a representation about Vioxx. The pictorial presentation of a hand (an X-ray image with superimposed red markings at the joints) makes a representation or suggestion about the use of Vioxx.

Therefore, DDMAC considers both advertisements to be full product ads and in violation of the Act for the following reasons:

- they fail to provide adequate information regarding the product's approved indication and usage,
- they fail to include risk information,
- they fail to present a brief summary of necessary information related to side effects, contraindications, and effectiveness, or provide adequate provision for the dissemination of full product labeling in connection with the broadcast ad.

**Fosamax : Broadcast Ad-Script #2 "No title"**

DDMAC considers this ad to be a product specific ad, because the advertisement in its entirety clearly identifies Fosamax. Although this ad does not mention Fosamax directly, the statement, "But there is a medication with the power to rebuild bones and reduce the risk of fractures" implicates only Fosamax as the drug with both of these particular effects. Therefore, DDMAC considers this advertisement to be a full product ad and in violation of the Act for the following reasons:

- it fails to provide the name (proprietary and established) of the drug,
- it fails to provide adequate information regarding Fosamax's approved indication and usage,
- it fails to include risk information,
- it fails to present a brief summary of necessary information related to side effects, contraindications, and effectiveness, or provide adequate provision for the dissemination of full product labeling in connection with the broadcast ad.

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Merck & Co., Inc.

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Merck should immediately cease using these and all other promotional materials for Fosamax and Vioxx that contain the same or similar claims or presentations. Merck should submit a written response to DDMAC, on or before July 30, 1999, describing its intent and plans to comply with the above. In its letter to DDMAC, Merck should include a list of all promotional materials that were discontinued, and the discontinuation date.

Merck should direct its response to the undersigned by facsimile at (301) 594-6771, or by written communication at the Division of Drug Marketing, Advertising, and Communications, HFD-40; Room 17B-20; 5600 Fishers Lane; Rockville, MD 20857. DDMAC reminds Merck that only written communications are considered official.

In all future correspondence regarding this matter, please refer to MACMIS#8086, NDA 20-560, and NDA 21-042.

Sincerely,

A handwritten signature in black ink, appearing to read "M. Misocky", with a long horizontal flourish extending to the right.

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