DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FOI

TRANSMITTAL VIA FACSIMILE

JUN - 4 1998

Lisa A. Luther
Director, Pharma Development Regulatory
Hoffmann-La Roche, Inc.
340 Kingsland Street
Nutley, New Jersey 07110-1199

Dear Ms. Luther:

As part of its routine monitoring program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has become aware of promotional materials for Roche Pharmaceuticals (Roche) posted on the World Wide Web[1] that violate the Federal Food, Drug, and Cosmetic Act (the Act) and its implementing regulations. Specifically, on Roche's web site there is a listing of prescription drug products that includes the indications for the products. However, the site does not present any balancing information about risks associated with the products. In addition, there is no disclosure of approved product labeling for the products.

The web site list was not submitted with FDA Form 2253 by Roche to FDA at the time of dissemination and is therefore in violation with 21 CFR 314.81 Post-marketing reporting.

To address these violations, Roche should immediately remove the web site or modify the web site to comply with the Act and regulations. Additionally, Roche should modify any other promotional materials, such as hard copy lists of prescription drugs, that may contain the same violations as the web site.

Roche should submit a written response to DDMAC on or before June 18, 1998, indicating its commitment to correct its violative promotional materials.

Roche should address its correspondence to the undersigned by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising, and Communications, HFD-40, Rm 17B-20, 5600 Fishers Lane, Rockville, MD, 20857.

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[1] http://www.roche.com/pharma/Products_Rx.htm

In future correspondence regarding this matter, please refer to MACMIS ID #6717.

Sincerely,

Melissa M. Moncavage
Division of Drug Marketing,
Advertising, and Communications