DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC - 3 1997

**TRANSMITTED VIA FACSIMILE**

Robin Conrad
Program Director
Drug Regulatory Affairs
Hoffmann-La Roche
340 Kingsland Street
Nutley, New Jersey 07110-1199

**RE: NDA 20-828**
Fortovase (saquinavir) Capsules
MACMIS ID # 6092

Dear Ms. Conrad:

As part of our routine monitoring and surveillance activities, the Division of Drug Marketing, Advertising and Communications (DDMAC) has reviewed a brochure entitled "Saquinavir: The Promise of Power" submitted by Hoffmann-La Roche (Roche) under cover of 2253 for Fortovase.

DDMAC has determined that this brochure is in violation of the Federal Food, Drug, and Cosmetic Act and the applicable regulations. Our specific objections to the brochure are discussed below and should apply to all applicable promotional materials for Fortovase.

The brochure is misleading because it lacks fair balance and minimizes important risk information found in the CONTRAINDICATIONS, WARNINGS, AND PRECAUTIONS sections of the approved product labeling.

- The statement "...AND FEW ADVERSE DRUG INTERACTIONS" understates the possibility for serious and life threatening events that are associated with concurrent administration of Fortovase and other drugs that are listed in the CONTRAINDICATION section of the approved product labeling.

- Roche has not included important risk information that is found in the WARNINGS section of the approved product labeling for Fortovase. In addition to including the most frequently reported adverse events for Fortovase, Roche should include risk information that discusses new onset diabetes, exacerbation of pre-existing diabetes and hyperglycemia, as well as hemophilia, in promotional materials.

- Roche has not included information that is found in the PRECAUTIONS section of the approved product labeling concerning administration of Fortovase in patients with hepatic insufficiency.

Overall, the entire presentation of this promotional piece lacks sufficient fair balance with regard to the risk information. The regulations state that promotional material should present information relating to side effects and contraindications with a prominence and readability reasonably comparable with the presentation of information relating to the effectiveness of the drug.

In order to address these objections, DDMAC recommends that Roche take the following actions:

1. Immediately discontinue the distribution of any and all promotional pieces that lack the risk information that is specified above.

2. Provide to DDMAC, in writing, Roche's intent to comply with the statute and regulations so that all promotional materials for Fortovase will present a fair and balanced discussion of the product.

3. Provide DDMAC with a list of pieces that will be discontinued.

Roche's response should be received by December 15, 1997. If Roche has any questions or comments, please contact the undersigned by facsimile at (301) 594-6771, or in writing at DDMAC, HFD-40, Room 17B-20, 5600 Fishers Lane, Rockville, MD 20857.

In all correspondence related to this matter, please refer to MACMIS ID #6092, in addition to the NDA number.

Sincerely,

Victoria J. Babb, Pharm.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications