



JAN 12 1998

TRANSMITTED VIA FACSIMILE

Thomas Watson
Drug Regulatory Affairs
Hoffman-La Roche Inc.
340 Kingsland Street
Nutley, New Jersey 07110-1199

RE: **NDA# 20-697**
Tasmar (tolcapone) Tablets
MACMIS# 5939

Dear Mr. Watson:

Reference is made to Hoffman-La Roche Inc.'s (Roche) recent "Coming Soon" advertisement that appeared in the September 1997 issues of *Archives of Neurology* and *Neurology Reviews*. The Division of Drug Marketing, Advertising, and Communications (DDMAC) has determined that this advertisement is in violation of the Federal, Food, Drug, and Cosmetic Act (the Act) and regulations promulgated thereunder. Specifically, the claims in this advertisement constitute pre-approval promotion of the new drug, Tasmar.

Section 312.7 of title 21 of the Code of Federal Regulations states that a "sponsor or investigator, or any person acting on behalf of a sponsor or investigator, shall not represent in a promotional context that an investigational drug is safe or effective for the purposes for which it is under investigation or otherwise promote the drug." DDMAC has traditionally recognized two methods by which sponsors may discuss products under FDA review without making prohibited promotional claims of safety or efficacy: institutional advertisements and "Coming Soon" advertisements. "Coming Soon" advertisements announce the name of the product and do not make any written, verbal, or graphic representations about its safety, efficacy, or intended use.

This advertisement is not considered a "Coming Soon" advertisement because it makes several representations about the product's intended use and its mechanism of action. Tasmar will be the first and only catecholamine-o-methyltransferase (COMT) inhibitor indicated for Parkinson's disease. Thus, the graphic presentation of the inhibition of COMT, both in the flow chart and in the pharmacokinetics

Mr. Thomas Watson
Hoffman-La Roche Inc.
NDA 20-697 (MACMIS 5939)

page 2

profile, makes a product-specific representation about Tasmar. Further, the claim that an "important new development in levodopa metabolism" is "coming soon from Roche" is a product-specific representation of Tasmar. Finally, if there could be any doubt that the drug product in question was intended for use in therapy for Parkinson's disease, this advertisement is a derivative of a current full product advertisement that Roche uses for Laridopa (levodopa) Tablets.

DDMAC requests that Roche immediately suspend any further dissemination or publication of this, and all materials with similar violative messages, until Tasmar is cleared for marketing. Roche should respond, in writing, with its intent to comply with DDMAC's request by January 22, 1998. Roche's response should include a list of all publications carrying this advertisement, and similarly violative messages, and a description of the methods for discontinuing their use.

If Roche has any questions or comments, please contact 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. DDMAC reminds you that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID #5939 in addition to the NDA number.

Sincerely,

Lisa L. Stockbridge, Ph.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications