DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-697

Hoffman-La Roche Inc.
Attention: Thomas Watson
340 Kingsland Street
Nutley, New Jersey 07110-1199

JAN 29 1998

Dear Mr. Watson:

Please refer to your new drug application dated June 03, 1996, and your resubmission dated July 28, 1997 and received July 30, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tasmar (tolcapone) 100 mg & 200 mg tablets.

We acknowledge receipt of your submissions dated:

July 30, 1997	September 2, 1997	September 12, 1997
October 21, 1997	December 5, 1997	

The User Fee goal date for this application is January 30, 1998.

This new drug application provides for the following indication:

Tasmar™ is indicated as an adjunct to levodopa and carbidopa for the treatment of the signs and symptoms of idiopathic Parkinson's disease.

The effectiveness of Tasmar™ was demonstrated in randomized controlled trials in patients receiving concomitant levodopa therapy with carbidopa or another aromatic amino acid decarboxylase inhibitor who experienced end of dose wearing-off phenomena as well as in patients who did not experience such phenomena.

We have completed the review of this application, including the submitted draft labeling, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed draft labeling. Accordingly, the application is approved effective on the date of this letter.

We remind you that Tasmar has been approved for a product expiration date of 24 months.

The final printed labeling (FPL) must be identical to the enclosed draft labeling. Marketing the product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or

similar material. For administrative purposes, this submission should be designated "FINAL PRINTED LABELING" for approved NDA 20-697. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

In addition, please submit three copies of the introductory promotional material that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to the Division of Neuropharmacological Drug Products and two copies of both the promotional material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising and Communications, HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Teresa Wheelous, R.Ph., Regulatory Management Officer, at (301) 594-2850.

Sincerely yours,

Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research