CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-087 / S-016
21-246 / S-010

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-087/S-016
NDA 21-246/S-010

Hoffmann-La Roche Inc.
Attention: Lynn DeVenezia-Tobias
Program Manager, Drug Regulatory Affairs
340 Kingsland Street
Nutley, New Jersey 07110-1199

Dear Ms. DeVenezia-Tobias:

Please refer to your supplemental new drug applications dated December 23, 2003, received December 24, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for of the Federal Food, Drug, and Cosmetic Act for Tamiflu® (oseltamivir phosphate) capsules and dry powder for suspension.

We acknowledge receipt of your submissions dated January 14, 2004, May 19, 2004, and June 9, 2004.

These supplemental new drug applications provide for revisions to the **Animal Toxicology, Precautions, Dosage and Administration,** and **Microbiology** sections of the package insert. In addition, revisions have been made to the **What is TAMIFLU?** and **Who should not take TAMIFLU?** sections of the patient package insert.

We have completed the review of these supplemental applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert and patient package insert).

Please submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount fifteen of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 21-087/S-016 and NDA 21-246/S-010." Approval of these submissions by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Jeff D. O'Neill, Regulatory Health Project Manager, at (301) 827-2362.

Sincerely,

{See appended electronic signature page}

Debra Birnkrant, M.D.
Division Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Jeffrey Murray
6/24/04 11:46:22 AM