CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-087 / S-008
21-246 / S-003

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-087/S-008
NDA 21-246/S-003

Hoffmann-La Roche Inc.
Attention: Joanna Waugh
Program Director
Drug Regulatory Affairs
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Ms. Waugh:

Please refer to your May 21, 2001 supplemental new drug applications submitted under section 505(b) for Tamiflu® (oseltamivir phosphate) 75 mg Capsules and 12 mg/mL Oral Suspension.

We acknowledge receipt of your submissions dated May 30, 2001 and July 3, 2001.

The special supplements: Changes Being Effected (S-008 and S-003) dated May 21, 2001, provide for the following changes to the package insert:

- Information regarding treatment of influenza in geriatric patients.
- Information regarding dosing of renally impaired patients with suspension formulation for prophylaxis of influenza.
- Clarification on age for pediatric indication.

We have completed the review of these special supplements 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 final printed labeling dated May 30, 2001. Accordingly, the supplemental new drug applications are approved effective on the date of this letter.

If you have any questions, contact Ms. Grace N. Carmouze, Regulatory Project Manager, at (301) 827-2335.

Sincerely,

{See appended electronic signature page}

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

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

/s/

Debra Birnkrant
7/24/01 11:45:52 AM
NDA 21-087, NDA 21-246