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APPLICATION NUMBER:

21-087 / S-005
21-087 / S-006
21-246 / S-001

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-087/S005
NDA 21-087/S-006
NDA 21-246/S-001

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 December 8, 2000 and December 21, 2000 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 June 8, 2001.

The special supplement: Changes Being Effected (S-005) dated December 8, 2000, provides for the deletion of ethanol and purified water from the list of constituents in the DESCRIPTION section of the labeling.

We note that this submission has been superceded by supplement S-006 dated December 21, 2000. Therefore, we will not review this supplement application but it will be retained it in our files.

The special supplement: Changes Being Effected (S-006) dated December 21, 2000 provides for changes to the package and patient package inserts approved under NDA 21-246. NDA 21-246, approved on December 14, 2000, provides for an oral suspension formulation for Tamiflu and a pediatric indication. In addition, this special supplement revises the pediatric dosing table to include "Recommended Dose for 5 days" as a header.

The special supplement: Changes Being Effected (S-001) dated December 21, 2000 revises the pediatric dosing table to include "Recommended Dose for 5 days" as a header.

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 June 8, 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
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NDA 21-246, 001, 21-087, 006