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APPLICATION NUMBER:

21-087 / S-009
21-246 / S-004

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-087/S-009
NDA 21-246/S-004

Hoffmann-La Roche, Inc.
Attention: Joanne Waugh
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Ms. Waugh:

Please refer to your supplemental new drug applications dated July 9, 2001, received July 10, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tamiflu® (oseltamivir phosphate) Capsules and Oral Suspension.

These "Changes Being Effected" supplemental new drug applications provide for revised wording in the ADVERSE REACTIONS: Observed During Clinical Practice for Treatment section of the label.

We have completed the review of these applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the applications are approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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 call 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 SLR 004, NDA 21-087 SLR 009