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APPLICATION NUMBER:

21-246 / S-002

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-246/S-002

Hoffmann-La Roche, Inc.
Attention: Duane L. Voss
340 Kingsland St.
Nutley, NJ 07110-1199

Dear Ms. Voss:

Please refer to your supplemental new drug application dated March 2, 2001, received March 5, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tamiflu® (oseltamivir phosphate) Suspension, 12 mg/mL.

This supplemental new drug application provides for deletion of the uniformity of dosage units by content uniformity from the release testing for each batch of Tamiflu Suspension.

We have completed the review of this supplemental application, and it is approved.

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, call Grace N. Carmouze, Regulatory Project Manager, at (301) 827-2335.

Sincerely,

{See appended electronic signature page}

Stephen P. Miller, Ph.D.
Chemistry Team Leader for the
Division of Antiviral Drug Products, (HFD-530)
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

Stephen Paul Miller
7/5/01 02:53:28 PM
21-246 S-002 is approved