DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-087/S-048 and S-049
NDA 21-246/S-034 and S-035

SUPPLEMENT APPROVAL

Hoffmann-La Roche Inc.
Attention: Sukirti D. Mukheja, B.S., Pharm.D.
Senior Program Manager
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Dr. Mukheja:

Please refer to your supplemental new drug applications dated May 29, 2009 and August 7, 2009, received June 1, 2009 and August 10, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for TAMIFLU (oseltamivir phosphate) 30 mg, 45 mg and 75 mg capsules and 12 mg/mL oral suspension.

We also acknowledge receipt of your submissions dated December 16, 2009, December 17, 2009, January 11, 2010, January 15, 2010, January 18, 2010, February 1, 2010, February 5, 2010 and February 22, 2010.

These "Prior Approval" supplemental new drug applications provide for the conversion of the package insert to PLR and incorporating labeling changes based on data from the following clinical studies:

- NV20235: "A randomized, controlled, multi-center trial of oseltamivir versus placebo for the seasonal prophylaxis of influenza in immunocompromised patients"

- NV20236: "An open label trial to treat children ages 1-12 for seasonal prophylaxis during influenza season"

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

Within 14 days from the date of this letter, please amend all pending supplemental applications for this NDA, including pending "Changes Being Effected" (CBE) supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format that includes the changes approved in this supplemental application.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm

LETTERS TO HEALTH CARE PROFESSIONALS

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

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

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 Robert G. Kosko, Jr., Regulatory Project Manager, at (301) 796-3979 or at the Division's main number (301) 796-1500.

Sincerely,

{See appended electronic signature page}

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

Enclosure
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21246	SUPPL-35	HOFFMANN LA ROCHE INC	TAMIFLU (OSELTAMIVIR PHOSPHATE) 12MG/ML
NDA-21246	SUPPL-34	HOFFMANN LA ROCHE INC	TAMIFLU (OSELTAMIVIR PHOSPHATE) 12MG/ML
NDA-21087	SUPPL-49	HOFFMANN LA ROCHE INC	TAMIFLU 75 MG CAPSULES
NDA-21087	SUPPL-48	HOFFMANN LA ROCHE INC	TAMIFLU 75 MG CAPSULES

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

/s/

DEBRA B BIRNKRANT
02/22/2010