DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-087/S-047
NDA 21-246/S-033

Hoffmann-LaRoche Inc.
Attention: S. Elizabeth Lucini, Pharm.D.
Program Manager, Drug Regulatory Affairs
340 Kingsland Street
Nutley, NJ 07110
Dear Dr. Lucini:

Please refer to your supplemental new drug application dated August 29, 2008, received September 2, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tamiflu (oseltamivir phosphate) Capsules.

This "Changes Being Effected" supplemental new drug application provides a statement regarding resistance mutations in the INDICATIONS AND USAGE section of the Package Insert. These revisions were requested by FDA on July 25, 2008.

We also refer to the September 25, 2008 letter from FDA approving the supplement for NDA 21-087. We are amending the approval letter to include NDA 21-246 and to include the PPI (last approved January 17, 2008) for inclusion on the Drugs@FDA website. Please also note that we are backdating this letter to the original action date and time plus 1 minute.

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

CONTENT OF LABELING
As soon as possible, but no later than 14 days from the date of this letter, please amend any pending applications for Tamiflu (NDA 21-087/S-045 and NDA 21-246/S-031) with content of labeling in structured product labeling (SPL) format to include the changes approved in this application.

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted August 29, 2008).

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 www.fda.gov/cder/ddmac.

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
Suite 12B05
5600 Fishers Lane
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 Elizabeth Thompson, MS, Regulatory Project Manager, at (301) 796-0824.

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 (clean copy of approved label)

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
9/25/2008 04:48:19 PM
NDA 21-087, 21-246