DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-087/S-056
NDA 21-246/S-039

SUPPLEMENT APPROVAL

Hoffmann-La Roche, Inc.
Attention: Susan Batcha
Program Director, Drug Regulatory Affairs
340 Kingsland Street
Nutley, NJ 07110-1199

Dear Ms. Batcha:

Please refer to your Supplemental New Drug Applications (sNDAs) dated September 20, 2010, received September 21, 2010 and October 29, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for TAMIFLU (oseltamivir phosphate) Capsules and Oral Suspension.

We acknowledge receipt of your amendments dated November 22, 2010, December 17, 2010, February 11, 2011, February 15, 2011, February 24, 2011 and March 16, 2011.

These Prior Approval supplemental new drug applications provide revisions to the Package Insert, Patient Information and the Carton and Container labeling based on a change in the concentration of the constituted Tamiflu for Oral Suspension from 12 mg/mL to 6 mg/mL, a change to volumetric dosing (from mg to mL), and a change in the Emergency Compounding instructions and final concentration (from 15 mg/mL to 6 mg/mL).

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

At the time the 6 mg/mL oral suspension is introduced to the market, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert, text for the patient package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at

http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the carton and immediate container labels submitted on March 16, 2011, except with the revisions listed below, as soon as they are available, but no more than 30 days after they are printed.

Revisions to Carton/Container Labeling (These revisions were sent by electronic mail to the applicant on March 18, 2011. The applicant responded by electronic mail on March 21, 2011 and agreed to make the changes listed below):

Carton and container label

1. Please use bold font for: "60 mL (usable volume after constitution)."

Carton label

2. Please use bold font for: "SHAKE WELL BEFORE EACH USE," and "Each mL contains 6 mg oseltamivir base after constitution."

3. On the "Note to pharmacist:" side panel include a usable volume statement of "60 mL (usable volume after constitution)" to appear spaced below the preparation directions.

4. Include the statement "New Strength" on the principal display panel and on at least one other panel. Other panels to consider would include the large panel opposing the principal display panel or the top flap panel. We recommend the color red is utilized to highlight this "New Strength" statement either by printing the statement in red or displaying red as a background color. The statement should be printed on labeling that is anticipated to be introduced into the marketplace during the first 6 months of distribution. The statement may alert or serve as a reminder to pharmacists and pharmacy technicians that a new strength / concentration was introduced into the marketplace.

Please submit these labels electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 21-087/S-056 and NDA 21-246/S-039**." Approval of this submission by FDA is not required before the labeling is used.

MARKET PACKAGE

Please submit one market package of the drug product when it is available.

If sending via USPS, please send to:

Elizabeth Thompson
Food and Drug Administration
Center for Drug Evaluation and Research
White Oak Building 22, Room: 6234
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

If sending via any carrier other than USPS (e.g., UPS, DHL), please send to:

Elizabeth Thompson
Food and Drug Administration
Center for Drug Evaluation and Research
White Oak Building 22, Room: 6234
10903 New Hampshire Avenue
Silver Spring, Maryland 20903

PROMOTIONAL MATERIALS

We recommend you request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) 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

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html; instructions are provided on 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 decide to 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, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

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, M.S., 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

ENCLOSURES:
Content of Labeling (clean)
Carton and Container Labeling (draft clean-*revisions to be sent in officially by applicant)

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
03/21/2011