NDA 021246/S-055

APPROVAL LETTER

Hoffmann-La Roche, Inc.
Attention: Peggy Omoruan
Associate Program Director, Regulatory Affairs
1 DNA Way
South San Francisco, CA 94080

Dear Ms. Omoruan:

Please refer to your Supplemental New Drug Application (sNDA) dated and received February 26, 2021, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Tamiflu (oseltamivir phosphate) Oral Solution, 6 mg/mL.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the addition of (b) (4) (b) (4) an alternate analytical facility for drug product release and stability testing.

APPROVAL

We have completed our review of this supplemental application. This supplement is approved.

We remind you that you must comply with reporting requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Omolara Laiyemo, Regulatory Business Process Manager, at (240) 402 - 3842.

Sincerely,

{See appended electronic signature page}

David Lewis, Ph.D.
Chief, Branch II
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

David Lewis

Digitally signed by David Lewis
Date: 8/10/2021 04:00:33PM
GUID: 508da72000029f287fa31e664741b577