CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-246 / S-006

ADMINISTRATIVE DOCUMENTS AND CORRESPONDENCE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-246/S-006

CBE-30 SUPPLEMENT

Hoffmann-La Roche Inc.
Attention: Duane L. Voss
Program Director
340 Kingsland Street
Nutley, New Jersey 07110

Dear Ms. Voss,

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Tamiflu® (oseltamivir phosphate) for Oral Suspension

NDA Number: 21-246

Supplement number: S-006

Date of supplement: August 31, 2001

Date of receipt: September 4, 2001

This supplemental application was submitted as a "Supplement - Changes Being Effected in 30 days." The appropriateness of reporting the proposed change(s) as changes being effected in 30 days is under review.

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on November 4, 2001in accordance with 21 CFR 314.101(a).

All communications concerning this supplement should be addressed as follows:

U.S. Postal Service:
Center for Drug Evaluation and Research
Division of Antiviral Drug Products, HFD-530
Attention: Division Document Room
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Antiviral Drug Products
Attention: Document Room
9201 Corporate Boulevard
Rockville, Maryland 20850

If you have any question, call Grace Carmouze, Regulatory Project Manager, at (301) 827-2335.

Sincerely yours,

Anthony W. DeCicco, R.Ph.
Chief, Project Management Staff
Division of Antiviral Drug Products
Center for Drug Evaluation and Research

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

/s/

Tony DeCicco

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