CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-087 / S-011

ADMINISTRATIVE DOCUMENTS AND CORRESPONDENCE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-087/S-011

PRIOR APPROVAL SUPPLEMENT

Hoffmann-La Roche Inc.
Attention: Duane L. Voss
Program Director, Drug Regulatory Affairs
340 Kingsland Street
Nutley, New Jersey 07110-1199

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) Capsules

NDA Number: 21-087

Supplement number: S-011

Date of supplement: November 27, 2001

Date of receipt: November 28, 2001

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 January 27, 2002 in 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, HFD-530
Attention: Document Room
9201 Corporate Blvd.
Rockville, Maryland 20850

If you have any questions, please 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