CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-246 / S-002

ADMINISTRATIVE DOCUMENTS AND CORRESPONDENCE

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-246/S-002

PRIOR APPROVAL SUPPLEMENT

Hoffmann-La Roche Inc.
Attention: Duane L. Voss
Program Director
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) for Oral Suspension 12mg/mL
NDA Number:	21-246
Supplement number:	S-002
Date of supplement:	March 2, 2001
Date of receipt:	March 5, 2001

This supplemental application proposes the following change: the deletion of the test *Uniformity of dosage units by content unformity*, which is performed as a released test for each batch.

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 May 1, 2001 in accordance with 21 CFR 314.101(a).

All communications concerning this supplement should be addressed as follows:

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 Boulevard
Rockville, Maryland 20850

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

Sincerely,

Anthony W. DeCicco, R.Ph.
Chief, Project Management Staff
Division of Antiviral Drug Products, HFD-530
Center for Drug Evaluation and Research
Food and Drug

/s/

Tony DeCicco
3/9/01 01:25:34 PM