

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-087 / S-005

21-087 / S-006

21-246 / S-001

ADMINISTRATIVE DOCUMENTS
AND
CORRESPONDENCE



**Memorandum of Project Manager's Labeling Review of Labeling Supplement
Division of Antiviral Drug Products**

NDA Number: 21-087/S-006

Date of Submission: December 21, 2000
Date Completed: June 21, 2001

Applicant: Hoffmann-La Roche Inc.
340 Kingsland Street
Nutley, New Jersey 07110-1199

Product Name: Tamiflu® (oseltamivir phosphate) 75 mg Capsule

Materials Reviewed: Final Printed Labeling submitted December 21, 2000

Background:

Labeling Supplement-Changes Being Effected (S-006), submitted on December 21, 2000, provides for changes to the package and patient inserts to implement the changes approved under NDA 21-246, which included a new formulation and new indication for Tamiflu. Tamiflu for Oral Suspension™ was approved on December 14, 2000, and provided for dosing in pediatric patients one year and older. The purpose of this review is to outline these changes throughout the labeling.



**Memorandum of Project Manager's Labeling Review of Labeling Supplement
Division of Antiviral Drug Products**

NDA Number: 21-246/S-001

Date of Submission: December 21, 2000
Date Completed: June 21, 2001

Applicant: Hoffmann-La Roche Inc.
340 Kingsland Street
Nutley, New Jersey 07110-1199

Product Name: Tamiflu (oseltamivir phosphate) for Oral Suspension™
12mg/mL

Materials Reviewed: Final Printed Labeling dated December 21, 2000

Review:

Labeling Supplement-Changes Being Effected (S-001), dated December 21, 2000, provides for the change in the dosing table for pediatric patients to include the header "Recommended Dose for 5 Days". For minor editorial changes, please see the attached document comparison.

Conclusions/Recommendations:

It should be conveyed to the applicant that the proposed revision in the December 21, 2000 Final Printed Labeling (FPL) is acceptable.

Grace N. Carmouze
Regulatory Project Manager
Division of Antiviral Drug Products

Supervisory Comment/Concurrence:

Anthony W. DeCicco, R.Ph.
Chief, Project Management Staff
Division of Antiviral Drug Products

Attachments:

Document comparison between December 14, 2000 draft labeling and December 21, 2000 Final Printed Labeling
Clean copy of December 21, 2000, Final Printed Labeling.

WITHHOLD 38 PAGE(S)

Draft Labeling

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

/s/

Grace Carmouze
7/18/01 10:52:00 AM
CSO

review

Tony DeCicco
7/31/01 11:44:33 AM
CSO