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APPLICATION NUMBER:

21-087 / S-008
21-246 / S-003

MEDICAL REVIEW

Medical Officer Review
Of
Proposed Labeling Changes to the Tamiflu Label

Date Submitted: 05/21/01
Date Completed: 06/05/01

Resume

In this submission Roche proposed the following labeling revisions which previously had been discussed with and concurred by the division during teleconferences:

1. To add the results of geriatric clinical trials to section 'Geriatric Patients' under Description of Clinical Studies

2. To state the suspension formulation of Tamiflu for prophylaxis of influenza as an alternative to capsule formulation in patients with creatinine clearance between 10 and 30 mL/min. While a study to investigate dosing regimens in patients undergoing routine hemodialysis or continuous peritoneal dialysis is ongoing, there are no recommended dosing regimens for patients with end-stage renal disease (i.e., creatinine clearance < 10 mL/min.)

In addition, the lower limit of age for pediatric population was clarified.

Regulatory Action

All the above changes are deemed acceptable.

Medical Officer

Teresa C. Wu, M.D., Ph.D.

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/s/

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7/17/01 12:51:24 PM
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