DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-088/S-001

Wyeth Pharmaceuticals Inc.
Attention: Donald G. Esherick
Director, Global Regulatory Affairs
35 Cambridge Park Drive
Cambridge, MA 02140

Dear Mr. Esherick:

Please refer to your new drug application dated July 12, 2007, received July 12, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Torisel™ Kit (temsirolimus) Injection.

This "Prior Approval" supplemental new drug application provides the draft text for the flag label that incorporated additional information in the container labels for both the diluent and active vials.

We completed our review of this supplemental new drug application. This supplement is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

IMMEDIATE CONTAINER LABELS

Submit final printed container labels that are identical to the submitted immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Container Labels for approved NDA 22-088/S-001**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded.

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Rebecca McKnight, Regulatory Health Project Manager, at (301) 796-1765.

Sincerely,

{See appended electronic signature page}

Hasmukh Patel, Ph.D.
Branch Chief
Branch 8, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

Enclosure

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

/s/

Hasmukh Patel

11/9/2007 10:00:13 AM