DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022088/S-002
NDA 022088/S-004
NDA 022088/S-005
NDA 022088/S-007
NDA 022088/S-010
NDA 022088/S-012

SUPPLEMENT APPROVAL

Pfizer Inc.
Attention: Michelle Yu, M.S., R.A.C.
Manager, Worldwide Regulatory Strategy
10646 Science Center Drive
San Diego, CA 92121

Dear Ms Yu:

Please refer to your Supplemental New Drug Applications (sNDA) dated May 12, 2008, received May 13, 2008; dated May 21, 2009, received May 21, 2009; dated May 22, 2009, received May 22, 2009; dated July 1, 2009, dated received July 1, 2009; dated December 17, 2009, received December 17, 2009; and dated June 14, 2010, received June 14, 2010; submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Torisel (temsirolimus) injection, 25 mg/mL.

We acknowledge receipt of your amendments dated July 17, 2009; May 12, 2010; June 18, 2010; April 11, 2011, April 28, 2011; May 17, 2011; May 20, 2011(2); May 26, 2011; June 13, 2011 and June 16, 2011.

This Prior Approval supplemental new drug application (S-002) provides for labeling revisions to the Highlights of Prescribing Information, Full Prescribing Information-Warnings and Precautions, Adverse Reactions, Drug Interactions, How Supplied and Patient Counseling Information Sections of the Package Insert.

This Prior Approval supplemental new drug application (S-004) provides for revisions to the Highlights of Prescribing Information, Full Prescribing Information-Warnings and Precautions, and Use in Specific Populations Sections of the Package Insert.

This Prior Approval supplemental new drug application (S-005) provides for revisions to the Highlights of Prescribing Information, Full Prescribing Information-Dosage and Administration and Dosage Forms and Strengths Sections of the Package Insert and to the Carton/Container Labeling.

This Prior Approval supplemental new drug application (S-007) provides for revisions to the Full Prescribing Information-Adverse Reactions Section of the Package Insert.

This Prior Approval supplemental new drug application (S-010) provides for revisions to the Highlights of Prescribing Information, Full Prescribing Information-Warnings and Precautions and Adverse Reactions Sections of the Package Insert.

This Changes Being Effected supplemental new drug application (S-012) provides revisions to the Full Prescribing Information-Adverse Reactions Sections of the Package Insert.

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert, text for the patient package insert, Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels and to the carton and immediate container labels submitted on May 26, 2011, 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 (June 2008)." 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 "**Product Correspondence – Final Printed Carton and Container Labels for approved NDA 022088/S-002, NDA 022088/S-004, NDA 022088/S-005, NDA 022088/S-007, NDA 022088/S-010 and NDA 022088/S-012**." Approval of this submission by FDA is not required before the labeling is used.

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html; instructions are provided on page 2 of the form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

REPORTING REQUIREMENTS

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

If you have any questions, call Modupe Fagbami, Regulatory Project Manager, at (301) 796-1348.

Sincerely,

{See appended electronic signature page}

Amna Ibrahim, M.D.
Deputy Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

ENCLOSURES:
Content of Labeling
Carton and Container Labeling

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

/s/

AMNA IBRAHIM
06/16/2011