DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

SEP 13 2006

Our STN: BL 103694/5065

Wyeth Pharmaceuticals, Incorporated
Attention: Joyce Schwenk, MT (ASCP), MPA
Manager, Global Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19101

Dear Ms. Schwenk:

Your request to supplement your biologics license application for Oprelvekin to revise the WARNINGS and ADVERSE REACTIONS section of the package insert to add information on ventricular arrhythmias and on changes in visual acuity in patients experiencing papilledema, and to revise the patient package insert to add information on changes in visual acuity, has been approved.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, and the text for the patient package insert). Marketing product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

We acknowledge your written commitment to as described in your letter of September 13, 2006, as outlined below:

Postmarketing Studies subject to reporting requirements of 21 CFR 601.70.

To conduct a study to evaluate the impact of Oprelvekin dosing on QT interval prolongation. The study should include up to 60 patients with cancer for whom Oprelvekin is indicated, who will receive Oprelvekin as subcutaneous injections at the recommended dose and schedule (50 μg/kg SC once daily until desired platelet response). Continuous cardiac monitoring (telemetry or Holter monitors) and/or concurrent detailed serial ECG monitoring, electrophysiologic studies, and serum Oprelvekin pharmacokinetic assessments will be performed at multiple timepoints prior to and during Oprelvekin administration. Timepoints will include, but are not limited to, pre-treatment, the estimated Tmax of Oprelvekin, and a post therapy wash-out time point. Serial ECGs will be evaluated in triplicate and read by a qualified physician. A study protocol will be provided by November 30, 2006. Patient accrual will be completed by October 30, 2008, the study will be completed by January 30, 2009, and a final study report will be submitted by April 30, 2009.

We request that you submit the clinical protocol to your IND, with a cross-reference letter to this biologics license application (BLA), STN BL 103694. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to your BLA STN BL 103694. Please use the following designators to label prominently all submissions, including supplements, relating to these postmarketing study commitments as appropriate:

- Postmarketing Study Protocol
- Postmarketing Study Final Report
- Postmarketing Study Correspondence
- Annual Report on Postmarketing Studies

For each postmarketing study subject to the reporting requirements of 21 CFR 601.70, you must describe the status in an annual report on postmarketing studies for this product. The status report for each study should include:

- information to identify and describe the postmarketing commitment,
- the original schedule for the commitment,
- the status of the commitment (i.e. pending, ongoing, delayed, terminated, or submitted),
- an explanation of the status including, for clinical studies, the patient accrual rate (i.e. number enrolled to date and the total planned enrollment), and
- a revised schedule if the study schedule has changed and an explanation of the basis for the revision.

As described in 21 CFR 601.70(e), we may publicly disclose information regarding these postmarketing studies on our Web site (http://www.fda.gov/cder/pmc/default.htm). Please refer to the February 2006 Guidance for Industry: Reports on the Status of Postmarketing Studies – Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997 (see http://www.fda.gov/cder/guidance/5569fnl.htm) for further information.

Any FDA approved patient labeling must be reprinted immediately following the last section of labeling or, alternatively, accompany the prescription drug labeling.

Please submit all final printed labeling at the time of use and include implementation information on FDA Form 356h. Please provide a PDF-format electronic copy as well as original paper copies (ten for circulars and five for other labels).

Please submit within 30 days content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text dated September 13, 2006. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

Please refer to http://www.fda.gov/cder/biologics/default.htm for important information regarding therapeutic biological products, including the addresses for submissions.

Effective August 29, 2005, the new address for all submissions to this application is:

Food and Drug Administration
Center for Drug Evaluation and Research
Therapeutic Biological Products Document Room
5901-B Ammendale Road
Beltsville, MD 20705-1266

This information will be included in your biologics license application file.

Sincerely,

Patricia Keegan

Patricia Keegan, M.D.
Director
Division of Biologic Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research