DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Our STN: BL 103694/5066

AUG 10 2006

Wyeth Pharmaceuticals, Incorporated
Attention: Victor J. Gangi
Director, Global Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Mr. Gangi:

Your request to supplement your biologics license application for Oprelvekin to replace the existing diluent vial with a new, pre-filled Sterile Water for Injection, USP (SWFI) diluent syringe for reconstitution of drug product and to revise the package insert, patient package insert, and carton labeling accordingly, has been approved.

We acknowledge your written commitment to provide additional information as described in your letter of August 9, 2006, as outlined below:

Postmarketing Studies not subject to reporting requirements of 21 CFR 601.70.

- To evaluate the effect on Neumega drug product of tungsten oxides present in the sWFI diluent syringe. The studies will be designed to determine whether the relevant tungsten oxides deposited during the syringe manufacturing process negatively impact product quality. If tungsten can oxidize drug product Wyeth will provide information that demonstrate appropriate control in the levels of tungsten. Results of these studies will be submitted to CDER by March 31, 2007.

Please submit 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).

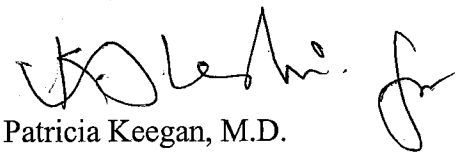
Please submit content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text dated August 3, 2006. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the Daily Med 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, Maryland 20705-1266

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

Sincerely,



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

Enclosures: Package Insert
Patient Package Insert
Carton Label
Diluent Syringe Label