DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

Our STN: BL 103951/5135

Amgen, Incorporated
Attention: Telly Chi, Pharm.D., M.S., RAC
Manager, Regulatory Affairs
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

APR 10 2007

Dear Dr. Chi:

Your request to supplement your biologics license application for Darbepoetin alfa to include a precautionary statement in the US package insert (USPI) about the possibility of allergic reactions due to dry natural rubber exposure (a derivative of latex contained within the needle cover of the prefilled syringe) has been approved.

Pursuant to 21 CFR 201.57(f)(2), patient labeling must be reprinted at the end of the package insert.

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

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

Sincerely,

Rafel Dwaine Rieves, M.D.
Acting Director
Division of Medical Imaging and Hematology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research