



Our STN: BL 103234-5076

Amgen, Incorporated
Attention: Douglas Hunt
Director, Regulatory Affairs
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

NOV 10 2004

Dear Mr. Hunt:

SUBMISSION TRACKING NUMBER (STN) BL 103234/5076 has been assigned to your recent supplement to your biologics license application for Epoetin alfa received on October 12, 2004. This acknowledgment recognizes that your submission is in the form of a Prior Approval Labeling Supplement as described under 21 CFR 601.12(f)(1).

Your request to supplement your biologics license application for Epoetin alfa to revise the package insert to update the Pharmacokinetics subsection of the Clinical Pharmacology section to include the pharmacokinetic profile of Epoetin alfa in neonates has been approved.

This fulfills your commitment to complete a literature search to find additional references to support the pharmacokinetic profile of Epoetin alfa in neonates as stated in commitment number 2 of the January 3, 1997, approval letter.

Pursuant to 21 CFR 201.57(f)(2), patient labeling must be reprinted at the end of the package insert. We request that the text of information distributed to patients be printed in a minimum of 10 point font.

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 important information regarding therapeutic biological products, including the addresses for submissions. Effective October 4, 2004, the new address for all submissions to this application is:

CDER Therapeutic Biological Products Document Room
Center for Drug Evaluation and Research
Food and Drug Administration
12229 Wilkins Avenue
Rockville, Maryland 20852

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

Sincerely,

(b)(6)

Patricia Keegan, M.D.

Director

Division of Therapeutic Biological Oncology Products

Office of Drug Evaluation VI

Center for Drug Evaluation and Research

Enclosures: Package Insert