DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

Our Reference No.: 97-0006

July 26, 1999

N. Kirby Alton, Ph.D.
Amgen, Inc.
1840 DeHavilland Drive
Thousand Oaks, CA 91320-1789

Dear Dr. Alton:

Your request to supplement your biologics license application for Epoetin alfa to include a revised package insert describing pediatric use has been approved.

We acknowledge your commitment of April 21, 1999 to revise the patient information leaflet for both EPOGEN® (Epoetin alfa) and PROCRIT® (Epoetin alfa) to provide full disclosure of information for self administration and your commitment of May 11, 1999 to complete your literature search to find additional references to support the pharmacokinetic profile of Epoetin alfa in neonates. We agree that you should include any relevant articles resulting from this search in the package insert at the next revision, and submit a supplement – Changes Being Effected.

Please submit three copies of final printed labeling at the time of use and include part II of the label transmittal form with completed implementation information.

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

Sincerely yours,

Karen D Weiss

Karen D. Weiss, M.D.
Director
Division of Clinical Trial
Design and Analysis
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