



Our STN: BL 103951/5088

DEC 15 2005

Amgen, Incorporated
Attention: Telly Chi, PharmD, MS, RAC
Senior Specialist, Regulatory Affairs
One Amgen Center Drive
Thousand Oaks, CA 91320-1799

Dear Dr. Chi:

Your request to supplement your biologics license application for Aranesp[®] to modify the product label to incorporate pediatric pharmacokinetic data and the results of a clinical study that examined the safety and efficacy of Darbepoetin alfa among pediatric patients with chronic renal failure (CRF) who were transitioned from treatment with Epoetin alfa to Darbepoetin alfa, has been approved. In addition, the modification of the Dosage and Administration section of the product label to incorporate new dosage information for pediatric patients, has been approved.

This fulfills your commitment to conduct and submit the results of a Phase 4 study (Study 200000100) to assess the pharmacokinetics, safety and efficacy of the darbepoetin alfa in pediatric patients as stated in commitment number five of the September 17, 2001, approval letter for STN 103951/5088.

We acknowledge your agreement to conduct post-marketing study as described in your letter of December 13, 2005, as outlined below:

1. To conduct a study, such as a single-arm open-label study or a prospective patient registry, to evaluate the safety and usefulness of Aranesp[®] for initial treatment for the correction of anemia in pediatric chronic renal failure patients. The draft protocol will be submitted to the FDA by June 30, 2006, and the study report will be submitted to the FDA by April 30, 2009.

We request that you submit clinical protocols to your IND, with a cross-reference letter to this biologics license application (BLA), STN BL 103951. Submit nonclinical and chemistry, manufacturing, and controls protocols and all study final reports to your BLA STN BL 103951. 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), and
- an explanation of the status including, for clinical studies, the patient accrual rate (i.e. number enrolled to date and the total planned enrollment).

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 April 2001 Draft 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/cber/gdlns/post040401.htm>) for further information.

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).

The regulatory responsibility for review and continuing oversight for this product transferred from the Center for Biologics Evaluation and Research to the Center for Drug Evaluation and Research effective June 30, 2003. For further information about the transfer, please see <http://www.fda.gov/cder/biologics/default.htm>. Until further notice, however, all correspondence, except as provided elsewhere in this letter, should continue to be addressed to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Medical Imaging and Hematology Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

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

Sincerely,

A handwritten signature in black ink, appearing to read "George Mills". The signature is fluid and cursive, with a long horizontal stroke at the beginning.

George Mills, M.D., M.B.A.

Director

Division of Medical Imaging and Hematology Products

Office of Oncology Drug Products

Center for Drug Evaluation and Research

How should Aranesp® be stored?

Aranesp® should be kept in its original carton to protect it from light, and stored in the refrigerator at 2° to 8°C (36° to 46°F). Do not place Aranesp® in the freezer. Do not use a vial or prefilled syringe of Aranesp® that has been frozen, left in light, or improperly refrigerated. It is important that Aranesp® be stored and used as stated in these instructions. Contact your healthcare provider with any questions about storage.

When traveling, transport Aranesp® in its original carton in an insulated container with a coolant such as blue ice. To avoid freezing, make sure the Aranesp® vial or prefilled syringe does not touch the coolant. Once you arrive, your Aranesp® should be placed in a refrigerator as soon as possible.

[Amgen Logo]

Manufactured by:

Amgen Manufacturing, Limited, a subsidiary of Amgen Inc.
One Amgen Center Drive
Thousand Oaks, California 91320-1799

© 2002-2005 Amgen Inc. All rights reserved.

Issue Date: xx/xx/xxxx

V5