



Consumer Alert

March 29, 2007

Topic: FDA Revised Prescribing Information for Erythropoiesis-Stimulating Agents (ESA) Drugs

Recently, the U.S. Food and Drug Administration (FDA) announced revisions to the prescribing information for erythropoiesis-stimulating agents (ESAs) for the treatment of anemia, including Amgen's Aranesp[®] (darbepoetin alfa) and Epogen[®] (epoetin alfa), and Ortho-Biotech's Procrit[®] (epoetin alfa). These changes will include revisions to the product labeling including updated warnings, a new 'BOXED WARNING', and modifications to the dosing instructions. Highlights of the changes include:

- ✓ A recommendation to use the lowest dose that will gradually increase hemoglobin concentration to the lowest level sufficient to avoid the need for red blood cell transfusion.
- ✓ Warnings surrounding an increased risk of death and serious cardiovascular events when administered to target a hemoglobin of greater than 12 g/dL.
- ✓ Additional warnings regarding use in cancer patients and in patients receiving ESAs pre-operatively for reduction of allogeneic red blood cell transfusions have also been included in the boxed warning. Please refer to the respective product labels for complete information of the risks associated with therapy in these populations.

If you have any questions regarding the information in this announcement, please contact your GBS Customer Service Representative at (410) 832-1333 or (800) 337-4973.