

## FDA News

**FOR IMMEDIATE RELEASE**

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### FDA Strengthens Safety Information for Erythropoiesis-Stimulating Agents (ESAs)

The U.S. Food and Drug Administration (FDA) today issued a public health advisory outlining new safety information, including revised product labeling about erythropoiesis-stimulating agents (ESAs), widely-used drugs for the treatment of anemia. The drugs affected by the safety update are darbepoetin alfa (Aranesp) and epoetin alfa (Epogen and Procrit). (ESAs are genetically engineered forms of the naturally occurring human protein, erythropoietin. Natural erythropoietin is made by the kidney and increases the number of red blood cells).

FDA and the manufacturer of these products have agreed on revised product labeling that includes updated warnings, a new boxed warning, and modifications to the dosing instructions. The new boxed warning advises physicians to monitor red blood cell levels (hemoglobin) and to adjust the ESA dose to maintain the lowest hemoglobin level needed to avoid the need for blood transfusions. Physicians and patients should carefully weigh the risks of ESAs against transfusion risks.

Recently completed studies describe an increased risk of death, blood clots, strokes, and heart attacks in patients with chronic kidney failure when ESAs were given at higher than recommended doses. In other studies, more rapid tumor growth occurred in patients with head and neck cancer who received these higher doses.

In studies where ESAs were given at recommended doses, an increased risk of death was reported in patients with cancer who were not receiving chemotherapy and an increased risk of blood clots was observed in patients following orthopedic surgery.

"The agency is in the process of re-evaluating the safety of Aranesp, Epogen, and Procrit on the basis of the results of recent clinical studies," said Steven Galson, MD, MPH, director of FDA's Center for Drug Evaluation and Research. "The new studies provide significant new information for both prescribers and patients, and the new information applies to all ESAs, which share the same mechanism of action. The safety of these products will be discussed when the Oncologic Drugs Advisory Committee (ODAC) meets in May and further revisions to the labeling may occur after that meeting."

Safety concerns from earlier ESA studies were discussed during a 2004 meeting of the ODAC. Product labeling was previously revised in 1997, 2004, and 2005 to reflect new safety information.

The three drugs are approved to treat anemia in patients with chronic kidney failure and in patients with cancer whose anemia is caused by chemotherapy. Epogen and Procrit are approved for patients scheduled for major surgery to reduce potential blood transfusions and for the treatment of anemia due to zidovudine therapy in HIV patients. ESAs are not approved to treat the symptoms of anemia – including fatigue – in cancer patients, surgical patients, or those with HIV.

All three drugs are manufactured by Amgen Inc. of Thousand Oaks, California. Procrit is marketed and distributed by Ortho Biotech LP, a subsidiary of Johnson & Johnson.

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[Additional Information on Erythropoiesis Stimulating Agents \(ESA\)](#)

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