

FDA Approves Changes to ESA Labeling

On Nov. 8, 2007, the U.S. Food and Drug Administration (FDA) approved revised boxed warnings and other safety-related product labeling changes for erythropoiesis-stimulating agents (ESAs). These new statements address the risks that ESAs pose to patients with cancer and patients with chronic kidney failure.

For patients with cancer, the new boxed warnings emphasize that ESAs caused tumor growth and shortened survival in patients with advanced breast, head and neck, lymphoid and non-small cell lung cancer when they received a dose that attempted to achieve a hemoglobin level of 12 grams per deciliter (g/dL) or greater.

The boxed warnings also emphasize that no clinical data are available to determine whether there is a similar risk of shortened survival or increased tumor growth for patients with cancer who receive an ESA dose that attempts to achieve a hemoglobin level of less than 12 g/dL.

ACCC is thankful that the FDA has released this information for ESA labeling. However, major differences remain between the new FDA label and the CMS National Coverage Determination (NCD) on ESAs, and ACCC remains concerned over these differences. As we have previously mentioned, ACCC is concerned that the CMS NCD will increase the number of blood transfusions for patients, causing a strain on hospitals and the nation's blood supply.

For more information go to <http://www.fda.gov/cder/drug/infopage/RHE/default.htm>.