FDA approves new warnings on anemia drugs

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The U.S. Food and Drug Administration has approved revised warnings and labeling changes for the anemia drugs Aranesp, Epogen and Procrit.

The warnings on the erythropoiesis-stimulating agents address the risks that the drugs pose to patients with cancer or chronic kidney failure, the FDA said Friday in a release.

The FDA said the labeling changes include a statement that symptoms of anemia, fatigue and quality of life haven't been shown to improve in patients with cancer who are treated with ESAs.

Epogen, Procrit and Aranesp are approved to treat anemia in patients with chronic kidney failure and anemia caused by chemotherapy in certain patients with cancer. Epogen and Procrit are also approved for use in certain patients with anemia who are scheduled to undergo major surgery and for the treatment of anemia caused by zidovudine therapy in HIV patients.

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 or greater, the release said.