

FDA Warns Doctors about Anti-Anemia Drugs

WASHINGTON - The Food and Drug Administration called on physicians to warn cancer patients undergoing chemotherapy that certain anti-anemia drugs led to tumor growth and decreased survival in some patients.

At issue are drugs sold under the brand names Procrit, Epogen and Aranesp. These drugs are genetically engineered versions of a natural protein that increases the number of red blood cells. The drugs generated \$10 billion in sales last year.

The FDA said on Thursday (November 8, 2007) it approved several labeling changes for the drugs, which are commonly referred to as ESAs. For patients with cancer, the new label emphasizes that the drugs caused tumor growth and shortened survival in patients with advanced breast, head and neck, lymphoid and non-small cell lung cancer.

The patients at greater risk for the adverse effects received a dose that attempted to achieve a hemoglobin level of 12 grams per deciliter or greater. But the new boxed warning emphasizes that no clinical data is available that would exclude similar risks for patients getting smaller doses, FDA officials stressed.

The agency had approved new labels for the medicines in March. But the newest warning emphasizes the types of cancers affected, and it notes that the medicines did not improve the overall quality of life for patients.

ESAs are also used to treat patients with chronic kidney failure. The new boxed warning approved by the agency states that ESAs should be used to maintain a hemoglobin level between 10 and 12. Maintaining higher hemoglobin levels in patients with chronic kidney failure increases the risk of death and serious cardiovascular reactions such as stroke, heart attack or heart failure, the boxed warning states.

The three drugs are manufactured by Amgen Inc. of Thousand Oaks, Calif. Procrit is marketed and distributed by a subsidiary of Johnson & Johnson.

For more about the FDA warning go to:

<http://www.fda.gov/cder/drug/infopage/RHE/default.htm>