

*The following is a message from the FDA's Office of Oncology Drug Products Director, Dr. Richard Pazdur:*

On November 8, 2007, the U.S. Food and Drug Administration approved new *Boxed Warnings* and other safety-related product labeling changes for the erythropoiesis-stimulating agents Epogen, Procrit, and Aranesp. The revised labeling incorporates advice from an FDA advisory committee and expands upon labeling changes made in March, 2007.

Clinical trials conducted in patients with cancer have shown either decreased overall survival and/or an increased rate of tumor progression when ESAs are used in advanced breast, head and neck, lymphoid, and non-small cell lung malignancies. These trials were conducted to achieve hemoglobin levels greater than or equal to 12 g/dL. The new labeling emphasizes that clinical studies have not been conducted to exclude ESA-associated tumor progression or shortened survival when ESAs are dosed to achieve lower hemoglobin levels.

Prescribers should consider the risks of tumor progression and decreased survival in prescribing ESAs, especially since these risks have not been excluded with lower hemoglobin levels. These risks should be weighed against the potential need for red cell blood transfusions and their associated risks. FDA strongly recommends that prescribers discuss risks of ESA-associated tumor progression and shortened survival with patients prior to initiating or continuing ESA therapy. ESAs should be used in patients with cancer only when treating anemia specifically caused by chemotherapy and not other causes of anemia. ESAs should be discontinued once the patient's planned chemotherapy course has been completed.

New labeling also emphasizes that in cancer patients, ESAs have not been demonstrated in controlled clinical trials to improve symptoms of anemia, quality of life, fatigue or patient well-being.

Please see the FDA Healthcare Professional Sheet and other documents regarding evolving safety issues with ESAs, posted at <http://www.fda.gov/cder/drug/infopage/RHE/default.htm>. Full prescribing information, including the above changes, is available for Aranesp at <http://www.fda.gov/cder/foi/label/2007/103951s5164lbl.pdf> and for Epogen/Procrit at <http://www.fda.gov/cder/foi/label/2007/103234s5158lbl.pdf>. Note that the content of the labels for Epogen and Procrit are the same except for the proprietary name.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's MedWatch Reporting Program via an online form at <http://www.fda.gov/medwatch/report.htm>, by faxing (1-800-FDA-0178) or mailing the postage-paid Form 3500 available at <http://www.fda.gov/medwatch>, or by telephone (1-800-FDA-1088).