



Anemia in the News

FDA Requires Doctors to Advise Patients about ESA Risks and Benefits

Updated: February 18, 2010

The U.S. Food and Drug Administration (FDA) announced that they will soon require medical professionals prescribing erythropoiesis-stimulating agents (ESAs) to provide a *Medication Guide* to patients and to formally educate them about the drug's risks and benefits.

The FDA will be implementing their new standards as part of a risk evaluation and mitigation strategy (REMS) intended to support informed decisions between patients and professionals, and mitigate the risks associated with the use of anemia drugs. As part of the new standards, oncologists and professionals prescribing ESAs to treat anemic cancer patients will also be required to enroll in the ESA APPRISE Oncology program and complete a training module.

Visit the [Drug Safety Communication](#) released by the FDA for ESA prescribing information, detailed requirements included in the REMS, information about the ESA APPRISE Oncology program, and for a table of key safety studies which contributed to the FDA's decision.

Stay Tuned for More!

Check back for more information from NAAC about these upcoming rules for discussing the risks and benefits of anemia drugs with patients.

Or be the first to receive it by signing up for our newsletter [Anemia Alert](#), and stay on top of anemia news for you and your medical practice.

References

1. U.S. Food and Drug Administration. *Drug Safety Communication: Erythropoiesis-Stimulating Agents (ESAs): Procrit, Epogen and Aranesp*. [Link](#). Accessed: February 18, 2010.

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