

**FDA-approved Labels for ESAs: Comparison of Previous Label and New 11/08/2007 Label**

<b>Changes to Label</b>				
<b>Dose and Modifications</b>	<b>Epoetin Alfa (both dose schedules)</b>		<b>Darbepoetin Alfa (both dose schedules)</b>	
	<b>Old Label</b>	<b>New Label (11/08/2007)</b>	<b>Old Label</b>	<b>New Label (11/08/2007)</b>
Dose reductions	Decrease dose by 25% when Hb <b>approaches 12 g/dL</b> or Hb increases >1 g/dL in 2 wks	Decrease dose by 25% when Hb <b>reaches a level needed to avoid transfusion</b> or Hb increases >1 g/dL in 2 wks	Decrease dose by 40% of previous dose when <b>Hb exceeds 11 g/dL</b> or Hb increases >1 g/dL in 2 wks	Decrease dose by 40% of previous dose when <b>Hb reaches a level needed to avoid transfusion</b> or Hb increases >1 g/dL in 2 wks
Dose withholding	If Hb exceeds 12 g/dL, withhold dose <b>until Hb &lt;11 g/dL</b> ; restart dose at 25% below previous dose	If Hb exceeds 12 g/dL, withhold dose <b>until Hb approaches a level where transfusions may be required</b> ; restart dose at 25% below previous dose	If Hb exceeds 12 g/dL, withhold dose <b>until Hb=11g/dL</b> ; restart dose at 40% below previous dose	If Hb exceeds 12 g/dL, withhold dose <b>until Hb approaches a level where transfusions may be required</b> ; restart dose at 40% below previous dose
<b>No Changes to Label</b>				
<b>Dose and Modifications</b>	<b>Epoetin Alfa</b>		<b>Darbepoetin Alfa</b>	
Initial dose	150 U/kg SC TIW	40,000 U SC weekly	2.25 mcg/kg SC weekly	500 mcg SC Q3W
Dose increase	Increase dose to 300 U/kg TIW if no reduction in transfusion requirements or rise in Hb after 8 wks	Increase dose to 60,000 U SC weekly if no increase in Hb by $\geq 1$ g/dL after 4 wks of therapy, in the absence of a RBC transfusion	Increase dose to 4.5 mcg/kg if there is <1 g/dL increase in Hb after 6 wks	-